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(71) Applicant: BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM [US/US]; 201 W. 7th Street, Austin, TX 78701 (US).		
(72) Inventors: THRASH, William, J.; 9846 Cash Mountain Road, Helotes, TX 78023 (US). JONES, Daniel, L.; 4538 Spotted Oak Woods, San Antonio, TX 78249 (US).		Published <i>With international search report.</i>
(74) Agent: MORICO, Paul, R.; Arnold, White & Durkee, P.O. Box 4433, Houston, TX 77210 (US).		
(54) Title: <b>SELF-SEALED IRRIGATION SYSTEM</b>		
(57) Abstract		
<p>A self-sealed irrigation system for supplying a treatment fluid to a treatment site is disclosed. The system includes a flexible containment member (800) that has a delivery channel (814) which delivers treatment fluid to the treatment site, a sealing channel (822) supplied with a suction force, and a recovery channel (818). The delivery channel (814) delivers the treatment fluid to the treatment site. The recovery channel (818) removes spent treatment fluid from the treatment site. The sealing channel (822) hermetically seals the containment member to the body surface surrounding the area to be treated. The containment member (800) is designed such that any spent treatment solution which should by-pass the recovery channel (818) is drawn into the sealing channel (822) thereby preventing any treatment fluid from leaking to the outside environment. The containment member is connected to a suction pump which circulates treatment fluid through the treatment site, and a reservoir which supplies the treatment fluid to the system.</p>		

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# SELF-SEALED IRRIGATION SYSTEM

## FIELD OF THE INVENTION

5 The present invention relates generally to irrigation systems, and more particularly, is directed to a self-sealed irrigation system adaptable for both intraoral and extraoral uses such as treating wounds, topical medication applications, site soakings, and the like.

## BACKGROUND OF THE INVENTION

Known devices have been used for circulating treatment solutions in a closed system. For example, devices  
10 known as surgical wound dams have been used for the irrigation of surgical wounds. These devices are typically formed of rubber and are bound tightly to the wound site with a bandage. These devices include an oval-shaped rubber member adapted for delivering fluids to the surgical wound. The rubber delivery member has a permeable membrane on the surface opposite the surgical wound through which fluid is delivered to the wound and an outer annular wall which seals the oval-shaped rubber member to the skin. An inlet tube and an outlet tube connected to the  
15 rubber delivery member are provided for delivering fluid to, and removing fluid from, respectively, the surgical wound site so that fluid can be recirculated to that site.

A drawback of these devices is that they do not apply the treatment solution uniformly over the treatment site. A further drawback of these devices is that they are susceptible to leaks. They provide no means for removing treatment solution which may escape the suction force of the outlet tube and leak past the permeable membrane. Also,  
20 should leakage occur in such a device, it is likely to interfere with the seal formed between the annular wall and the treatment site.

Closed irrigation systems have also been used in the area of dental treatment. These systems were developed to provide effective and safe means of treating the dentoalveolar structures with chemo-therapeutic rinses while avoiding ingestion of the rinses into the digestive tract of the patient.

25 The benefits of using oral chemo-therapeutic rinses in the treatment of a variety of oral maladies has long been recognized. For example, fluoride solutions have been applied to teeth for years in order to prevent or arrest the

progression of dental caries. More recently, chlorahexidine solutions have been developed to combat gingivitis and periodontal disease. These solutions, as well as many other oral rinses, are agents in the prevention, treatment, and healing process of dentoalveolar structures.

A drawback of prior oral irrigation systems is that they have a tendency to leak causing the chemo-  
5 therapeutic rinses to be ingested into the digestive tract. This can cause undesirable side effects. For example, if ingested in a sufficient quantity and concentration, fluoride can cause gastrointestinal distress. Chlorahexidine can impair a person's ability to taste foods. The tremendous topical value of these agents is therefore mitigated by the potential side effects that might result if these agents are inadvertently ingested.

One known oral irrigation system utilizes a mouthpiece shaped to conform to the contours of the dentition. In  
10 this system, the treatment solution is pumped under high frequency pulsations to a chamber disposed within the mouthpiece. The chamber interconnects with a series of channels having outlets arranged along the mouthpiece so that the solution is ejected onto different areas of the teeth. The spent solution is evacuated through a second series of strategically placed outlets to a second chamber within the mouthpiece. An inlet tube and outlet tube connect the chambers of the mouthpiece to a pump which functions to circulate the solution through the mouthpiece in a closed  
15 system.

A drawback of this prior art device is that the space between the mouthpiece and the teeth is very small. This requires that an individualized mouthpiece be constructed for each patient. Thus, the device is incapable of being mass produced and hence is costly to manufacture. Furthermore, the mouthpiece of this device only covers the teeth and inter dental papillae thus limiting treatment to these areas. Accordingly, the device is not capable of covering, and thus  
20 not capable of treating, all of the entire dentoalveolar structures. Moreover, this prior art device suffers from the drawback of limiting both the volume and pressure of the solution which can be supplied to the treatment area.

Another drawback of this device is that it is not self-sealing. It relies on the suction emanating from the liquid return portion of the device, i.e., the second series of outlets, for both removing the spent solution and sealing the mouthpiece to the teeth and gums. This device does not provide a separate sealing mechanism which holds the

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mouthpiece in place and provides a barrier to the external environment. Consequently, the device is susceptible to leaks and is thus unreliable.

The present invention is directed to overcoming or at least minimizing some of the problems mentioned above.

5

#### SUMMARY OF THE INVENTION

In one embodiment of the present invention, a self-sealed irrigation system for general application is disclosed. The system supplies a treatment fluid, which may be either a liquid or a gas, to a treatment site utilizing a containment member which may take any one of the many forms described further herein. The flexible containment member includes a delivery channel which delivers the treatment fluid to the treatment site, a recovery channel supplied with a suction force, which removes the treatment solution from the treatment site and a sealing channel that hermetically seals the containment member to the treatment site. A delivery inlet coupling is provided which connects the delivery channel to a delivery pump external to the containment member. A recovery outlet coupling is also provided which connects the recovery channel to a suction pump external to the containment member. A suction outlet coupling is further provided for connecting the sealing channel to the suction pump. In one embodiment, the suction pump may also function as the delivery pump.

In another embodiment of the present invention, a self-sealed oral irrigation system for oral use is disclosed. It includes a reservoir of treatment fluid, a suction pump and a generally U-shaped mouthpiece which is formed to cover the dentoalveolar structure to be treated. The mouthpiece includes a delivery channel having a plurality of holes which deliver treatment fluid to the dentoalveolar structure to be treated, a recovery channel supplied with a suction force for removing the spent treatment solution, and a sealing channel which surrounds the dentoalveolar structure and hermetically seals the mouthpiece to the patient's gums. The recovery channel has a plurality of holes equally spaced along the perimeter of the mouthpiece through which spent treatment solution is removed from the dentoalveolar structure. The sealing channel may either be open or closed having a plurality of suction ports. A suction pump is connected to the mouthpiece via couplings and is coupled to a fluid reservoir.

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The present invention also provides a method of irrigating a treatment site with a treatment fluid in a closed system. The method includes the steps of hermetically sealing the treatment site from an outside environment with a sealing means utilizing a suction force, delivering treatment fluid from a reservoir to the treatment site and applying the treatment fluid to the treatment site. The method also includes the steps of removing spent treatment solution from the treatment site through a recovery means. Any spent treatment solution which may have escaped the recovery means is then removed through the sealing means which preferably surrounds the entire treatment site, so as to prevent leakage of the spent treatment solution to the outside environment. The method also includes the step of purifying spent treatment solution for recirculation through the system.

**BRIEF DESCRIPTION OF THE DRAWINGS**

10 The foregoing and other features of the present invention will be best appreciated with reference to the detailed description of the invention, which follows when read in conjunction with the accompanying drawings, wherein:

Figure 1 is a diagram of a recirculating sealed irrigation system for general application according to the present invention.

15 Figure 2 is a cross-sectional view of a containment hood used in the recirculating sealed irrigation system shown in Figure 1.

Figure 3 is a bottom perspective view of the containment hood shown in Figure 2.

Figure 4A is a partial enlarged view of one embodiment of the sealing means and treatment solution removal means portion of the containment hood shown in Figure 2.

20 Figure 4B is a partial enlarged view of another embodiment of the sealing means and treatment solution removal means portion of the containment hood shown in Figure 2.

Figure 5 is a perspective view of a flexible containment member having a three channel design according to the present invention.

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Figure 6 is a top view of the flexible containment member shown in Figure 5.

Figure 7 is a cross-sectional view of the flexible containment member shown in Figure 6 taken along line 7-7.

Figure 8 is a top view of an alternate embodiment of the flexible containment member having a three channel design according to the present invention.

5       Figure 9 is a cross-sectional view of yet another embodiment of the flexible containment member having a three channel design according to the present invention.

Figure 10 is yet another cross-sectional view of another embodiment of the flexible containment member having a three channel design according to the present invention.

Figure 11 is a top view of a flexible containment member having a two channel design.

10      Figure 12 is a cross-sectional view of the containment member shown in Figure 11 taken along line 12-12.

Figures 13-15 are cross-sectional views of three other embodiments of the flexible containment member having a two channel design.

Figure 16 is a diagram of an irrigation system employing the three channel design flexible containment member having a three channel design according to the present invention.

15      Figure 17 is an irrigation system employing the flexible containment member having a two channel design according to the present invention.

Figure 18 shows a modification of the flexible containment member according to the present invention which is adapted to fit around the foot and ankle portion of a patient's leg.

20      Figure 19 shows a modified embodiment of the flexible containment member according to the present invention which is adapted to fit around the hand and wrist portion of a patient's hand.

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Figure 20 is a diagram of a recirculating sealed oral irrigation system used for dental treatment according to the present invention.

Figure 21 is a top perspective partial cross-sectional view of a mouthpiece used in the recirculating sealed oral irrigation system shown in Figure 20.

5       Figure 22 is a cross-sectional view of the mouthpiece shown in Figure 21.

Figure 23 is a cross-sectional view of the mouthpiece shown in Figure 21 covering the dentoalveolar structures.

Figure 24 is a diagram of an alternate embodiment of a recirculating sealed oral irrigation system used for dental treatment according to the present invention.

10      Figure 25 is a perspective view of another embodiment of a mouthpiece having a three channel design according to the present invention.

Figure 26 is a top view of the embodiment of the mouthpiece shown in Figure 25.

Figure 27 is a cross-sectional view of the embodiment of the mouthpiece shown in Figure 26 taken along line 27-27.

15      Figure 28 is a cross-sectional view of an alternate embodiment of the mouthpiece having a three channel design according to the present invention.

Figure 29 is a partial cross-sectional partial perspective view of another embodiment of the mouthpiece having a three channel design according to the present invention.

20      Figure 30 is a partial cross-sectional partial perspective view of yet another embodiment of the mouthpiece having a three channel design according to the present invention.

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Figure 31 is a perspective view of another embodiment of a mouthpiece having a two channel design according to the present invention.

Figure 32 is a top view of the embodiment of the mouthpiece shown in Figure 31.

Figure 33 is a partial cross-sectional partial perspective view of the embodiment of the mouthpiece shown in  
5 Figure 31 taken along line 33-33.

Figure 34 is a partial cross-sectional partial perspective view of another embodiment of the mouthpiece having a two channel design according to the present invention.

Figure 35 is a partial cross-sectional partial perspective view of yet another embodiment of the mouthpiece having a two channel design according to the present invention.

10 Figure 36 is a partial cross-sectional partial perspective view of yet another embodiment of the mouthpiece having a two channel design according to the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a sealed irrigation system which can be used in a variety of applications. One embodiment of the invention has a general application. This embodiment will be described first. A second 15 embodiment of the invention has a more specific application, namely for use in dental treatment. This latter embodiment will be described second.

Turning now to the drawings and referring initially to Figure 1, one embodiment of a sealed irrigation system according to the present invention is shown generally by reference numeral 10. The system 10 includes a containment hood 12, a delivery pump 14, a suction pump 16, and a solution reservoir 18 having a filter 20. As those of ordinary skill in the art will appreciate, the functions of the delivery pump 14 and the suction pump 16 may be performed by a 20 single vacuum pump.

The containment hood 12 is shaped in the form of an inverted funnel having a neck portion 22, a conical portion 24, and an outer rim portion 26 and is designed to fit around the site to be treated, as shown in Figure 2. The containment hood 12 is defined by an inner wall 28 and an outer wall 30, which are substantially parallel to one another at the neck portion 22, as shown in Figure 2. In the conical portion 24, the inner wall 28 and outer wall 30 diverge slightly from one another. Intake channels 32 are formed between the inner wall 28 and the outer wall 30 which, as will be explained further below, are connected to the suction pump 16 so as to provide a vacuum stream which produces suction to hold the containment hood 12 in place and seal it to the treatment site of the patient. The intake channels 32 also function to uptake excess treatment solution, as will be explained further below. The containment hood 12 is preferably formed of a flexible material, such as Silastic® silicon rubber manufactured by Dow-Corning.

A flexible disk-shaped membrane 34 having a plurality of apertures is disposed at the outer rim portion 26 of the containment hood 12 between the inner wall 28 and the outer wall 30, as shown in Figure 3. The flexible membrane 34 is preferably formed of rubber and may be integrally attached to the inner and outer walls 28 and 30 or alternatively may be removable. The flexible disk-shaped membrane 34 functions as a sealing ring which prevents leakage of the treatment solution to the outside environment.

A delivery channel 36 is provided at the neck portion 22 of the containment hood 12 which supplies a stream of treatment solution to the treatment site at a high velocity and pressure, e.g., 30 psi, as shown in Figure 2. As the stream of treatment solution exits the delivery channel 36 into the conical portion 24 of the containment hood 12, it dissipates forming a substantially uniform spray which is applied to the treatment site.

The treatment solution is removed from the treatment site by a flexible recovery ring 38 having a plurality of holes equally spaced around its perimeter, as shown in Figure 3. The recovery ring 38 is preferably tube-shaped and formed of rubber. It is disposed within, and along the perimeter of, the outer rim portion 26 of the containment hood 12. The plurality of holes in the recovery ring 38 are arranged along the inside of the ring, as shown in Figures 3 and 4A. In an alternate embodiment, the recovery ring 38 has a cut-out section along the inside of the ring in lieu of the plurality of equally spaced holes, as shown in Figure 4B. The recovery ring 38 is attached to the inner wall 28 via a

conduit 40, as shown in Figures 4A and 4B. The conduit 40 provides a fluid communication path between the recovery ring 38 and the intake channel 32.

As the uniform spray of treatment solution is applied to the treatment site it is removed through the holes in the recovery ring 38, as indicated by the arrows in Figure 2. The spent treatment solution is removed from the 5 treatment site by suction provided by the vacuum stream in the intake channel 32 which is supplied to the recovery ring 38 via the conduit 40. Because the holes in the recovery ring 38 are disposed along the inside of the ring and not the bottom of the ring, the recovery ring does not form a hermetic seal with the treatment site. This configuration enables spent treatment solution to be quickly and easily removed from the treatment site without the system "backing up", i.e., the treatment solution is removed from the treatment site at least as quickly as it is delivered to the treatment 10 site. Accordingly, wounds are repeatedly "rinsed" and tissue breakdown products and infection generated tissue fluids rapidly removed, thus aiding in healing the wound.

However, because a hermetic seal is not formed with the treatment site, some of the spent treatment solution might seep past the recovery ring 38. Leakage of the spent solution to the outside environment is prevented, however, by the seal formed between the flexible disk-shaped membrane 34 and the area surrounding the treatment site. Any 15 spent treatment solution which should by-pass the recovery ring 38 will be drawn into the intake channel 32 through the flexible disk-shaped membrane 34. This design provides a completely closed system which contains the treatment solution to the treatment site and prevents leakage of the solution to the outside environment.

Returning to a description of the system, the intake channel 32 is connected to the suction pump 16 via a conduit 42 which is preferably formed of a thermoplastic material, as shown in Figure 1. The delivery channel 36 is 20 connected to the delivery pump 14 via a conduit 44, also formed of a thermoplastic material. The delivery pump 14 and the suction pump 16 are connected to the treatment solution reservoir 18 via conduits 48 and 50, respectively. The filter 20 is provided within the reservoir 18 for purifying the treatment solution.

The treatment solution is circulated through the system as follows: The treatment solution is drawn from the reservoir 18 through the conduit 48 by the delivery pump 14 which transmits the solution through the conduit 44 to the

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delivery channel 36. As the treatment solution exits the delivery channel 36 into the conical portion 24 of the containment hood 12, it dissipates into a substantially uniform spray which is applied to the treatment site. The spent treatment solution is removed through the holes in the recovery ring 38. The spent solution is drawn through the conduit 40 to the intake channel 32. Any spent solution which seeps past the recovery ring 38 is drawn into the intake channel 32 through the flexible disk-shaped membrane 34. The spent solution is then transmitted through the conduit 42 to the suction pump 16. The suction pump 16 in turn delivers the spent treatment solution to the reservoir 18. Before the treatment solution is recirculated through the system it passes through, and is purified by, the filter 20.

As will be appreciated by those of ordinary skill in the art, there are alternate ways to construct the system according to the present invention. For example, as described above, the delivery pump 14 and the suction pump 16 may be combined into a single vacuum pump. Furthermore, the reservoir 18 and filter 20 may be incorporated into the pump thus forming a single recirculating unit which can be connected to the containment hood 12. In an alternative construction, two suction pumps may be provided, one which is connected via a conduit to the recovering ring 38 for removing the spent treatment solution, and the other which is connected to the intake channel 32 for sealing the containment hood 12 to the treatment site.

A number of other embodiments of the general irrigation system according to the present invention will now be discussed. The first alternate embodiment is shown in Figure 5. In this embodiment, a flexible containment member 100 is provided. The flexible containment member 100 is defined by a perimeter portion 102, which surrounds the area to be irrigated, a sealing surface 104, and a barrier member 106. The perimeter portion 102 preferably has a circular or oval shape, but may assume any desired shape.

An open channel 108 (also referred to generally as the sealing channel 108) is formed along the periphery of the perimeter portion 102, as best seen in Figures 6 and 7. The open channel 108 delivers a suction force for securing the flexible containment member 100 to the body surface to be treated. The open channel 108 forms a hermetic seal between the flexible containment member 100 and also functions to recover any spent treatment solution not recovered by the recovery means discussed below.

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A suction outlet coupling 110 (shown in Figures 5 and 6) is coupled to the perimeter portion 102 of the flexible containment member 100 and is in fluid communication with the open channel 108. The suction outlet coupling 110 is provided for coupling the flexible containment member 100 to a suction source, as further described below.

5 A delivery inlet coupling 112 is also coupled to the perimeter portion 102 of the containment member 100. The delivery inlet coupling 112 is in fluid communication with a delivery channel 114 formed in the perimeter portion 102, as shown in Figure 6. The delivery channel 114 is located above the open channel 108 and extends along at least a portion of the periphery of the perimeter portion 102, as shown in Figures 6 and 7. A plurality of delivery ports 116 are formed in the delivery channel 114 that deliver treatment solution to the body surface to be treated, as shown in  
10 Figure 6. The delivery inlet coupling 112 is provided for coupling the flexible containment member 100 to a fluid delivery source, as further described below.

A recovery outlet coupling 118 is further coupled to the perimeter portion 102 of the containment member 100, as shown in Figure 6. The recovery outlet coupling 118 is in fluid communication with a recovery channel 120 formed in the perimeter portion 102. The recovery channel 120 is located above the open channel 108 and extends along at least a portion of the periphery of the perimeter portion 102, as shown in Figures 6 and 7. A plurality of recovery ports 122 are formed in the recovery channel 120 that recover the treatment solution delivered to the body surface treated, as shown in Figure 6.  
15

The suction outlet coupling 110, delivery inlet coupling 112, and recovery outlet coupling 118 are all preferably integrally formed parts of the flexible containment member 100, but as those skilled in the art will appreciate, these components may alternatively be attached to the flexible containment member 100 as separate members. If formed as separate members, these components are preferably formed of a thermoplastic material. Like the containment hood 12, the flexible containment member 100 is preferably formed of Silastic® silicon rubber.  
20

The sealing surface 104 is a flat surface that form fits to the surface area to be treated when a suction force is applied to the open channel 108. It is defined by a pair of wing-shaped members that extend outward from the open

channel 108. The sealing surface 104 extends around the entire periphery of the perimeter portion 102, as best seen in Figure 6. The barrier member 106 is a thin fluid impermeable layer that contains the area enclosed by the perimeter portion 102. The barrier member 106 contains the fluid within an area defined as the internal chamber 124, which is best seen in Figure 7.

5 In another alternate embodiment of the present invention, the flexible containment member 100 has no recovery channel or corresponding recovery ports, as shown in Figure 8. Rather, the recovery outlet coupling 118 has a port 126 which allows spent treatment solution to be removed from the treatment area.

In another embodiment of the present invention, the open channel 108 is replaced with a closed channel 128 having a plurality of ports 130, as shown in Figure 9. In this configuration, the plurality of ports 130 supply the 10 suction force that seals the flexible containment member 100 to the body surface. This configuration has application for patients that have sensitive or irritated skin around the area to be treated. The design minimizes the area of skin exposed to the suction force, while ensuring a sufficient seal.

The embodiment shown in Figure 9 utilizes the design employing a recovery channel 120 and plurality of recovery ports 122. A modification of this design would be to replace the recovery channel 120 and plurality of 15 recovery ports 122 with the single recovery port 126 shown in Figure 8. This yet other embodiment of the present invention is shown in Figure 10.

The embodiments shown in Figures 5-10 incorporate a three channel design, i.e., the delivery channel 114, recovery channel 120, and sealing channel 108 are separated inside the flexible containment member 100. These embodiments may alternatively incorporate a two channel design. In the two channel design, the recovery channel 120 and sealing channel 108 are connected to one another inside the flexible containment member 100. This modified 20 design, as it applies to the various embodiments shown in Figures 5-10, is shown in Figures 11-15.

In the two channel design, there are only two couplings, a suction outlet coupling 210 and a delivery inlet coupling 212. The recovery outlet coupling 118 of the three channel design illustrated in Figures 5-10 is incorporated into the suction outlet coupling 210. The suction outlet coupling 210 supplies a suction force to both recovery channel

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220 and sealing channel 208, as shown in Figure 12. The recovery channel 220 is connected to the sealing channel 208 via conduit 225.

In the embodiment shown in Figures 11 and 12, the recovery channel 220 has a plurality of ports 222, and the sealing channel 208 is an open channel. In the embodiment shown in Figure 13, the recovery channel 220 has a plurality of ports 222 (not shown), and the sealing channel 208 is a closed channel 228 having a plurality of ports 230. In the embodiment shown in Figure 14, the recovery channel 220 and plurality of ports 222 are replaced with a single recovery port 226, and the sealing channel 208 is an open channel. In the embodiment shown in Figure 15, the recovery channel 220 and plurality of ports 222 are replaced with a single recovery port 226, and the sealing channel 208 is a closed channel 228 having a plurality of ports 230.

Figure 16 illustrates the three channel configuration of the flexible containment member 100 connected to a vacuum pump 300. The vacuum pump 300 supplies a suction force to the recovery channel 120 and the sealing channel 108. The suction force is supplied to the recovery channel 120 via conduits 302 and 304 and supplied to the sealing channel 108 via conduits 302 and 306. The conduits 304 and 306 are connected at one end to the conduit 302 at juncture 308 and connected at the other end to the recovery outlet coupling 118 and the suction outlet coupling 110, respectively. Valves 310 and 312 disposed in conduits 304 and 306, respectively, are provided to regulate the supply of suction force to the recovery channel 120 and sealing channel 108, respectively. The valves 310 and 312 are preferably variable flow valves.

The vacuum pump 300 also supplies compressed air to a solution reservoir 314 via a conduit 316. The treatment solution is supplied under pressure from the solution reservoir 314 to the delivery channel via conduit 318, which is connected to the flexible containment member 100 at the delivery inlet coupling 112. A valve 320 disposed within the conduit 318 regulates the supply of the treatment solution to the treatment area. As those of ordinary skill in the art will appreciate, the functions of the vacuum pump 300 may be shared between a delivery pump and a separate suction pump, as shown in Figure 1.

The treatment solution can either be passed through the treatment area or it may be confined to the treatment area under pressure. The treatment solution is preferably passed through the treatment area in cleansing operations. When it is desired to cause the treatment solution to be absorbed transdermally, however, then it is preferable to confine the treatment area under pressure.

5       The treatment solution is passed through the treatment area first by delivering the solution to the treatment area, and then by removing the treatment solution from the treatment area. This is accomplished by operating the vacuum pump 300 while the valves 310 and 320 are open. The valve 320 allows the treatment solution to be delivered to the treatment area, and the valve 310, by supplying a suction force to the treatment area, causes the treatment solution to be removed. During this operation, the valve 312 is open thereby supplying a suction force to the sealing  
10      channel 108 and sealing the flexible containment member 100 to the body surface.

The treatment solution is confined to the treatment area under pressure by opening the valves 312 and 320 and closing the valve 310. As discussed above, the valve 320 allows the treatment solution to be delivered to the treatment area, and the valve 312 supplies suction force to seal the flexible containment member 100 to the body surface. By closing the valve 310, the treatment solution cannot be removed from the internal chamber 124 (shown in  
15      Figures 7, 9 and 10) and thereby remains within the internal chamber 124 under pressure. When it is desired to remove the treatment solution from the internal chamber 124, the valve 310 is opened. As those of ordinary skill in the art will appreciate, a variety of different treatment methods are possible with the three channel design illustrated in Figure 16. This is made possible by the adjustability of the valves 310, 312 and 320.

Figure 17 illustrates the two channel configuration of the flexible containment member 100 connected to the  
20      vacuum pump 400. In this configuration, the suction force is supplied from the vacuum pump 400 to the flexible containment member 200 via a single conduit 402. The conduit 402 delivers the suction force to the suction outlet coupling 210, which, as described above, in turn delivers the suction force to the recovery channel 220 and sealing channel 208. A valve 404, disposed in the conduit 402, is provided for turning the suction force on and off. The vacuum pump 400 supplies compressed air to solution reservoir 414 via conduit 416. The treatment solution is then  
25      delivered to the treatment area under pressure from the solution reservoir 414 via conduit 406. A valve 408, disposed

in the conduit 406, is provided for regulating the supply of the treatment solution to the treatment area. With this configuration, the treatment solution may only be passed through the flexible containment member 200. Because the recovery channel 220 may not be shut off without also shutting off the supply of suction to the sealing channel 208, the treatment solution may not be confined to the internal chamber 224 under pressure with this arrangement.

5       The systems described above have universal application for the treatment of wounds, debridement, site soakings, topical administration of various liquid dedications as well as a variety of other applications. Other such applications include: rinsing for eye infections, rinsing for ear infections and wax removal, palliative irrigation for painful relief of gums, veterinary applications, hyperbaric oxygen delivery, delivery of antimicrobial rinses to many types of patients, treatment of athletes foot, treatment of infections in immune-compromisedpatients (e.g., HIV, organ 10 transplants), localized treatment of bed sores, hand and feet sores of diabetic patients, etc.

The configuration of the flexible containment member 100 may be modified to enclose virtually any treatment site. One specialized configuration is shown in Figure 18. In this embodiment, the containment member 100 takes the form of a boot 500 which fits over the foot and ankle of a patient. The boot 500 is provided with a delivery channel 514 having a plurality of ports 516, a recovery channel 520 having a plurality of ports 522, and a sealing channel 508, as well as all the other features of the above-described invention including a suction outlet coupling 510, a delivery inlet coupling 512, and a recovery outlet coupling 518. Furthermore, as those of ordinary skill in the art will appreciate, the boot 500 may take the form of any one or more of the embodiments described herein.

Another specialized configuration is shown in Figure 19. In this embodiment, the containment member 100 takes the form of a glove 600 which fits over the hand and wrist of a patient. The glove 600 is provided with a 20 delivery channel 614 having a plurality of ports 616, a recovery channel 620 having a plurality of ports 622, and a sealing channel 608, as well as all the other features of the above-described invention including a suction outlet coupling 610, a delivery inlet coupling 612, and a recovery outlet coupling 618. Furthermore, as those of ordinary skill in the art will appreciate, the glove 600 may take the form of any one or more of the embodiments described herein.

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In yet another embodiment of the present invention, a recirculating sealed oral irrigation system according to the present invention is shown in Figure 20. In this embodiment, the flexible containment member 100 is modified into a mouthpiece adaptable for covering dentoalveolar structures to be treated. Such a mouthpiece is shown generally in Figure 20 by reference numeral 760. The mouthpiece 760 has a generally U-shaped configuration which corresponds to the shape of the appropriate dentoalveolar structures and is preferably formed of a thermoplastic material, such as medical grade silicone, as shown in Figure 21. In the case of the upper jaw or maxilla, the mouthpiece 760 may be configured to cover the hard palate or only the teeth and gums depending on the treatment to be offered.

The cross-section of the mouthpiece 760 is generally canal-shaped being defined by a pair of side walls 762 and 764 and a bottom wall 766 disposed between the side walls, as shown in Figure 22. The pair of side walls 762 and 764 and the bottom wall 766 are in turn defined by an inner wall 768 and an outer wall 770. The inner wall 768 and the outer wall 770 are substantially parallel to one another. The space between the inner wall 768 and the outer wall 770 forms an intake channel 772 which is connected to the suction pump 716 via conduits 773 which are disposed along the perimeter of the mouthpiece 760.

The upper ends of each of the pair of side walls 762 and 764 project inwardly at a substantially right angle, so as to be substantially parallel to the bottom wall, as shown in Figure 22. In this region, the inner and outer walls 768 and 770 of the side walls 762 and 764 diverge from one another. Flexible membranes 774 and 776 having a plurality of apertures are disposed between the inner wall 768 and the outer wall 770 at the upper ends of each of the side walls 762 and 764, as shown in Figure 22. The flexible membranes 774 and 776 are preferably formed of rubber and may be integrally attached to the inner and outer walls 768 and 770 or alternatively may be removable. The flexible membranes 774 and 776 function as sealing strips which prevent leakage of the treatment solution from inside the mouthpiece 760 to the outside environment.

In this embodiment of the present invention, a pair of delivery tubes 778 and 780 are provided along the entire length of the bottom wall 766, as shown in Figure 21. Each of the pair of delivery tubes 778 and 780 has a plurality of apertures disposed along its entire length through which the treatment solution is discharged toward the

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teeth and gums, as shown in Figure 23. A pair of recovery tubes 782 and 784 are also provided along the entire length of the side walls 762 and 764, as shown in Figure 21. The recovery tubes 782 and 784 may have either a plurality of holes or a cut-out section (not shown) which is disposed along their entire length. The recovery tubes 782 and 784 are designed to abut against the gums (as shown in Figure 23) and function in much the same way as the recovery ring 38 does in the embodiment shown in Figures 1-4. The recovery tubes 782 and 784 are attached to the inner wall 768 via a conduit 786, as shown in Figure 22. The conduit 786 provides a fluid communication path between the recovery tubes 782 and 784 and the intake channel 772.

Although the configuration of the mouthpiece 760 is somewhat different from the flexible containment member 100, it functions in much the same way. The treatment solution is delivered to the mouthpiece 760 through the delivery tubes 778 and 780. It exits the apertures in the delivery tubes 778 and 780 striking the covered oral structures at an appropriate velocity and thereby treating them. The spent treatment solution is drawn away from the treatment area through the recovery tubes 782 and 784. Any treatment solution which should by-pass the recovery tubes 782 and 784 will be drawn up into the intake channel 772 through the flexible membranes 774 and 776. Although the recovery tubes 782 and 784 abut the gums, they do not form a hermetic seal with the gums, and therefore some leakage may occur. However, the flexible membranes 774 and 776 do form a hermetic seal with the gums, so that any treatment solution which by-passes the recovery tubes 782 and 784 will be drawn into the intake channel 772 by the suction provided by the suction pump 716.

The construction of the mouthpiece 760 is general and flexible allowing for one size to fit many mouths. This construction provides an increased space over prior art mouthpieces which allows for coverage of all of the dentoalveolar structures, not just the teeth and interdental papillae, as is the case with the prior art devices. This increased space also allows for greater therapeutic benefit via higher fluid volume applied, greater pressure generated, and more turbulence created.

The intake channel 772 is connected to the suction pump 716 via the conduit 742, as shown in Figure 20. The delivery tubes 778 and 780 are connected to the delivery pump 714 via the conduit 744. The delivery pump 714 and the suction pump 716 are connected to the reservoir 718 via the conduits 748 and 750, respectively.

In an alternate embodiment of the system just described, the mouthpiece 760 is connected to the conduits 742 and 744 at the curved section of the mouthpiece, as shown in Figure 24. Thermoplastic couplings 790 and 792 connect the conduits 742 and 744, respectively, to the mouthpiece 760.

Other embodiments of the mouthpiece 760 according to the present invention will now be described.

5 Referring to Figure 25, an alternate embodiment of the mouthpiece 760 according to the present invention is shown. In this embodiment, the mouthpiece is referred to by reference numeral 800. The mouthpiece 800 is manufactured by preparing a mold of the dentoalveolar structure to be treated and pouring a medical grade silicon material, e.g., Silastic® silicon rubber manufactured by Dow Corning, into the mold. The resultant mouthpiece 800 is generally U-shaped and is defined by a tooth conforming section 802, a gum conforming section 804 and a pallet conforming  
10 section 806.

A delivery inlet coupling 808, a recovery outlet coupling 810, and a suction outlet coupling 812 are all coupled to the curved portion of the mouthpiece 800. The delivery inlet coupling 808 delivers treatment solution under pressure to a delivery channel 814 formed along the inner surface of the tooth conforming section 802, as shown in Figure 26. A plurality of delivery ports 816 are formed along the delivery channel 814 for ejecting the treatment solution into the treatment area. The recovery outlet coupling 810 connects with a recovery channel 818, also formed along the inner surface of the tooth conforming section 802, which removes spent treatment solution from the mouthpiece 800. A plurality of recovery ports 820 are formed along the recovery channel 818 for this purpose.  
15

The suction outlet coupling 812 connects to a sealing channel 822 that is formed along the entire perimeter of the inner surface of the gum conforming section 804 of the mouthpiece 800. The sealing channel 822 may either be open, as shown in Figure 27, or it may be closed as shown in Figure 28. The applications of each embodiment has been previously described. In the embodiment shown in Figure 28, a plurality of suction ports 824, disposed along the sealing channel 822, supply the suction force to the patients gums for sealing the mouthpiece 800 in place. In the embodiment shown in Figure 27, the open channel configuration performs this function. The inner surface of the gum conforming section 804 is generally flat and form fits to the gums when a suction force is applied to the sealing  
20

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channel 822. It is defined by a pair of wing-shaped members 826 and 828 that are disposed on opposite sides of the sealing channel 822, as shown in Figures 27 and 28.

In another alternate embodiment of the present invention, the mouthpiece 800 has no recovery channel or corresponding recovery ports, as shown in Figure 29. Rather, the recovery outlet coupling 810 has a port 830 which 5 opens into the inside of the mouthpiece 800 and allows spent treatment solution to be removed from the treatment area. The embodiment shown in Figure 29 has an open sealing channel 822. This single recovery port design may also be utilized in the closed sealing channel configuration. This modified embodiment is shown in Figure 30.

The embodiments shown in Figures 25-30 incorporate a three channel design, i.e., the delivery channel 814, recovery channel 818, and sealing channel 822 are separated inside the mouthpiece 800. These embodiments may 10 alternatively incorporate a two channel design. In the two channel design, the recovery channel 818 and the sealing channel 822 are connected to one another inside the mouthpiece 800. This modified design, as it applies to the various embodiments shown in Figures 25-30, is shown in Figures 31-36.

In the two channel design, there are only two inlets, a suction outlet coupling 912 and a delivery inlet coupling 908. The recovery outlet coupling 810 of the three channel design illustrated in Figures 25-30 is incorporated 15 into the suction outlet coupling 912. The suction outlet coupling 912 branches off into two channels, recovery channel 918 and sealing channel 922 at juncture 935, as shown in Figure 33.

In the embodiment shown in Figures 32 and 33, the recovery channel 918 has a plurality of ports 920, and the sealing channel 922 is an open channel. In the embodiment shown in Figure 34, the sealing channel 922 is a closed channel having a plurality of suction ports 924. In the embodiment shown in Figure 35, the recovery channel 918 and 20 plurality of ports 920 are replaced with a single recovery port 930, and the sealing channel 922 is an open channel. In the embodiment shown in Figure 36, the recovery channel 918 and plurality of ports 920 are replaced with a single recovery port 930, and the sealing channel 922 is a closed channel having a plurality of suction ports 924.

The mouthpieces 800 and 900 described above, may be connected to the recirculation system as shown in Figure 20 or the circulation systems shown in Figures 16 and 17.

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There are a wide variety of uses of the oral application of the present invention. It can be used for aiding in cleaning the teeth of mentally retarded patients with massive dental disease. It can also be used for fluoride treatments for patients of all ages, particularly children and the elderly. Furthermore, it can be used with those having mental or physical disabilities or geriatric patients with arthritis who are not willing or able to perform routine oral hygiene tasks  
5 (e.g., brushing and flossing). It can be further used for the delivery of topical medications, such as chlorahexidine, hydrogen peroxide, saline and the like for the prevention and treatment of various oral maladies, particularly periodontal disease. It can be used in conjunction with virtually any type of dental treatment. The possible uses of the system are ever increasing as new medications suitable for oral use are developed.

While the present invention is susceptible to various modifications and alternative forms, a number of which  
10 have been discussed above, it should be understood that the invention is not intended to be limited to the particular forms disclosed. For example, although a delivery channel having one or more delivery ports is described in the preferred embodiments, as those of ordinary skill in the art will appreciate, other designs, such as a single delivery port, may be used. It is intended that the present invention cover all modifications, equivalents and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

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**CLAIMS:**

1. A self-sealed irrigation system for supplying a treatment fluid to a treatment site, comprising: a containment member that encloses the treatment site, the containment member further comprising:
  - (a) a delivery channel adapted to deliver treatment fluid to the treatment site;
  - 5 (b) a recovery channel adapted to remove the treatment fluid from the treatment site; and
  - (c) a sealing channel adapted to seal the containment member to the area surrounding the treatment site, said sealing channel being disposed in relation to said recovery channel so as to remove any treatment solution not removed by said recovery channel.
- 10 2. The self-sealed irrigation system as defined in claim 1, wherein the containment member further comprises a delivery inlet coupling that connects the delivery channel to a treatment fluid delivery source outside of the containment member, and at least one delivery port disposed along the delivery channel that ejects the treatment fluid into the treatment area.
- 15 3. The self-sealed irrigation system as defined in claim 1, wherein the containment member further comprises a recovery outlet coupling that connects the recovery channel to a suction source outside of the containment member, and at least one port disposed along the recovery channel through which treatment fluid from the treatment area enters the recovery channel.
- 20 4. The self-sealed irrigation system as defined in claim 1, wherein the containment member further comprises a suction outlet coupling that connects the sealing channel to a suction source outside of the containment member.
5. The self-sealed irrigation system as defined in claim 1, wherein the recovery channel is coupled in fluid communication with the sealing channel.

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6. The self-sealed irrigation system as defined in claim 1, wherein the sealing channel is a closed channel and further comprises at least one port.

7. The self-sealed irrigation system as defined in claim 1, wherein the containment member has an inverted 5 funnel shape, which is defined by a neck portion, a conical portion and a rim portion.

8. The self-sealed irrigation system as defined in claim 7, wherein the containment member has an inner wall and an outer wall, said inner wall and outer wall being substantially parallel to one another in the neck portion and diverging slightly from one another in the conical portion.

10

9. The self-sealed irrigation system according to claim 1, wherein the containment member is adapted to fit around the dentoalveolar structure.

15

10. The self-sealed irrigation system as defined in claim 1, further comprising a suction pump that is coupled to the delivery channel, recovery channel and sealing channel.

11. The self-sealed irrigation system as defined in claim 10, further comprising a treatment fluid reservoir coupled between the suction pump and the delivery channel.

20

12. The self-sealed irrigation system as defined in claim 1, further comprising a delivery pump that is coupled to the delivery channel and a suction pump that is coupled to the recovery channel and the sealing channel.

13. The self-sealed irrigation system as defined in claim 12, further comprising a treatment fluid reservoir coupled between the delivery pump and the suction pump.

25

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14. The self-sealed irrigation system as defined in claim 1, wherein the containment member is formed of a generally flexible material and has a generally circular shape.

15. The self-sealed irrigation system as defined in claim 1, wherein the containment member is configured in the  
5 shape of a boot that is adapted to fit over at least the foot portion of a patient's leg.

16. The self-sealed irrigation system as defined in claim 1, wherein the containment member is configured in the shape of a glove that is adapted to fit over at least the hand portion of a patient's arm.

10 17. A self-sealed irrigation system for supplying a treatment fluid to a treatment site, comprising: a containment member that encloses the treatment site, the containment member further comprising:

- (a) means for delivering treatment fluid to the treatment site,
- (b) means for removing the treatment fluid from the treatment site, and
- (c) means for supplying a suction force that seals the containment member to the area surrounding the  
15 treatment site.

18. The self-sealed irrigation system as defined in claim 17, wherein the delivery means includes a delivery inlet coupling, a delivery channel connected to the delivery inlet coupling and at least one delivery port disposed along the delivery channel.

20

19. The self-sealed irrigation system as defined in claim 17, wherein the recovery means includes a recovery outlet coupling, a recovery channel connected to the recovery outlet coupling and at least one recovery port disposed along the recovery channel.

25 20. The self-sealed irrigation system as defined in claim 17, wherein the recovery means includes a recovery port.

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21. The self-sealed irrigation system as defined in claim 17, wherein the suction supplying means includes a suction outlet coupling, and a sealing channel connected to the suction outlet coupling.

22. The self-sealed irrigation system as defined in claim 21, wherein the sealing channel is an open channel.

5

23. The self-sealed irrigation system as defined in claim 21, wherein the sealing channel is a closed channel and further comprises at least one port.

24. The self-sealed irrigation system as defined in claim 17, wherein the removing means is coupled in fluid communication with the suction supplying means.

10

25. A method of irrigating a treatment site with a treatment fluid, comprising the steps of:

(a) sealing the treatment site from an outside environment with a sealing means utilizing a suction force;

(b) applying the treatment fluid to the treatment site;

15 (c) removing spent treatment fluid from the treatment site utilizing a recovery means; and

(d) removing any spent treatment fluid which may escape the recovery means through the sealing means, so as to prevent leakage of the spent treatment solution to the outside environment.

26. The irrigation method as defined in claim 25, further comprising the step of  
20 delivering the spent treatment fluid from the treatment site to a reservoir.

27. The irrigation method as defined in claim 26, further comprising the step of purifying the spent treatment fluid.

25 28. The irrigation method as defined in claim 27, further comprising the step of delivering purified treatment fluid from the reservoir to the treatment site

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29. A self-sealed oral irrigation system for supplying a treatment fluid to the dentoalveolar structure, comprising:

(a) a mouthpiece adapted to fit around the dentoalveolar structure, the mouthpiece further comprising:

5 (i) at least one delivery channel having at least one opening for delivering treatment fluid to the dentoalveolar structure;

(ii) an intake channel supplied with a suction force;

10 (iii) a wall separating the at least one delivery channel from the intake channel;

(iv) a primary recovery channel coupled to the intake channel that at least partially surrounds the dentoalveolar structure, the primary recovery channel having at least one opening adapted to remove spent treatment fluid from the dentoalveolar structure; and

15 (v) a sealing channel coupled to the intake channel that surrounds the dentoalveolar structure and secures the mouthpiece to the dentoalveolar structure, the sealing channel having at least one opening adapted to draw any spent treatment fluid that may not be removed by the primary recovery channel into the intake channel; and

(b) a treatment fluid delivery apparatus coupled to the at least one delivery channel and adapted to supply the dentoalveolar structure with treatment fluid through the mouthpiece.

20 30. The self-sealed oral irrigation system as defined in claim 29, wherein the mouthpiece has a configuration which is generally U-shaped and a cross-section that is generally canal-shaped, and is defined by a pair of side walls and a bottom wall disposed between the side walls, the side walls having an upper end portion that conforms to the shape of the mouth.

25 31. The self-sealed oral irrigation system as defined in claim 30, wherein the pair of side walls are at least partially defined by an inner wall and an outer wall, said inner wall and outer wall being substantially parallel to one

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another along at least a portion of the side walls, and diverging from one another along the upper end portion of the side walls.

32. The self-sealed oral irrigation system as defined in claim 31, wherein the intake channel is formed by the  
5 space between the inner wall and the outer wall.

33. The self-sealed oral irrigation system as defined in claim 32, further comprising a flexible membrane disposed between the inner wall and the outer wall at the upper end portion of the side walls.

10 34. The self-sealed oral irrigation system as defined in claim 29, further comprising a conduit that connects the primary recovery channel to the intake channel.

35. The self-sealed oral irrigation system as defined in claim 29, wherein the primary recovery channel is a tube having a plurality of holes equally spaced around the perimeter of the mouthpiece.

15 36. The self-sealed oral irrigation system as defined in claim 29, wherein the treatment fluid delivery apparatus includes a vacuum pump, which is coupled to the at least one delivery channel and connected to the intake channel for supplying a suction force to the intake channel.

20 37. The self-sealed oral irrigation system as defined in claim 36, further comprising a reservoir coupled to the vacuum pump and having a filter for purifying the treatment fluid being circulated through the system.

38. A mouthpiece adapted to fit around the dentoalveolar structure for supplying a treatment fluid to the dentoalveolar structure, comprising:

25 (a) at least one delivery channel having at least one opening for delivering treatment fluid to the dentoalveolar structure;

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- (b) an intake channel adapted to supply a suction force;
- (c) a wall separating the at least one delivery channel from the intake channel;
- (d) a primary recovery channel coupled to the intake channel that at least partially surrounds the dentoalveolar structure, the primary recovery channel having at least one opening through which spent treatment fluid is removable from the dentoalveolar structure; and
- 5 (e) a sealing channel coupled to the intake channel that surrounds the dentoalveolar structure and secures the mouthpiece to the dentoalveolar structure, the sealing channel having at least one opening adapted to draw any spent treatment solution not removed from the primary recovery channel into the intake channel.

10

39. The mouthpiece as defined in claim 38, wherein the mouthpiece has a configuration that is generally U-shaped and a cross-section that is generally canal-shaped, and is defined by a pair of side walls and a bottom wall disposed between the side walls, the side walls having an upper end portion that conforms to the shape of the mouth.

15

40. The mouthpiece as defined in claim 39, wherein the pair of side walls are at least partially defined by an inner wall and an outer wall, said inner wall and outer wall being substantially parallel to one another along at least a portion of the side walls, and diverging from one another along the upper end portion of the side walls.

20 41. The mouthpiece as defined in claim 40, wherein the intake channel is formed by the space between the inner wall and the outer wall.

42. The mouthpiece as defined in claim 41, further comprising a flexible membrane that is disposed between the inner wall and the outer wall at the upper end portion of the side walls.

25

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43. The mouthpiece as defined in claim 38, further comprising a conduit that connects the primary recovery channel to the intake channel.

44. The mouthpiece as defined in claim 38, wherein the primary recovery channel has a plurality of holes that are equally spaced around the perimeter of the mouthpiece.

45. A mouthpiece adapted to fit around a dentoalveolar structure for supplying a treatment fluid to the dentoalveolar structure, comprising:

- (a) means for delivering treatment fluid to the dentoalveolar structure;
- (b) means for removing the treatment fluid from the dentoalveolar structure; and
- 10 (c) a sealing channel adapted to seal the mouthpiece to the gums, said sealing channel being disposed in relation to said removal means so as to remove any treatment solution not removed by said removal means.

46. The mouthpiece as defined in claim 45, wherein the mouthpiece is defined by a tooth conforming section, a gum conforming section and a palette conforming section.

47. The mouthpiece as defined in claim 46, wherein the delivery means and removal means are disposed in the tooth conforming section of the mouthpiece and at least a portion of the sealing channel is disposed in the gum conforming section.

20

48. The mouthpiece as defined in claim 47, wherein the removal means includes a recovery channel coupled to a recovery outlet coupling which is in turn connected to a suction pump external to the mouthpiece and at least one port through which spent treatment fluid may exit the treatment area.

49. The mouthpiece as defined in claim 47, wherein the removal means includes a port through which spent 25 treatment fluid may exit the treatment area.

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50. The mouthpiece as defined in claim 49, further comprising wing-shaped members that extend outward from the sealing channel and that are disposed around the periphery of the gum conforming section of the mouthpiece.

51. The mouthpiece as defined in claim 45, wherein the sealing channel is open.

5

52. The mouthpiece as defined in claim 45, wherein the sealing channel is closed and has a plurality of parts disposed therealong.

53. The mouthpiece as defined in claim 45, wherein the removal means is in fluid communication with the  
10 sealing channel.

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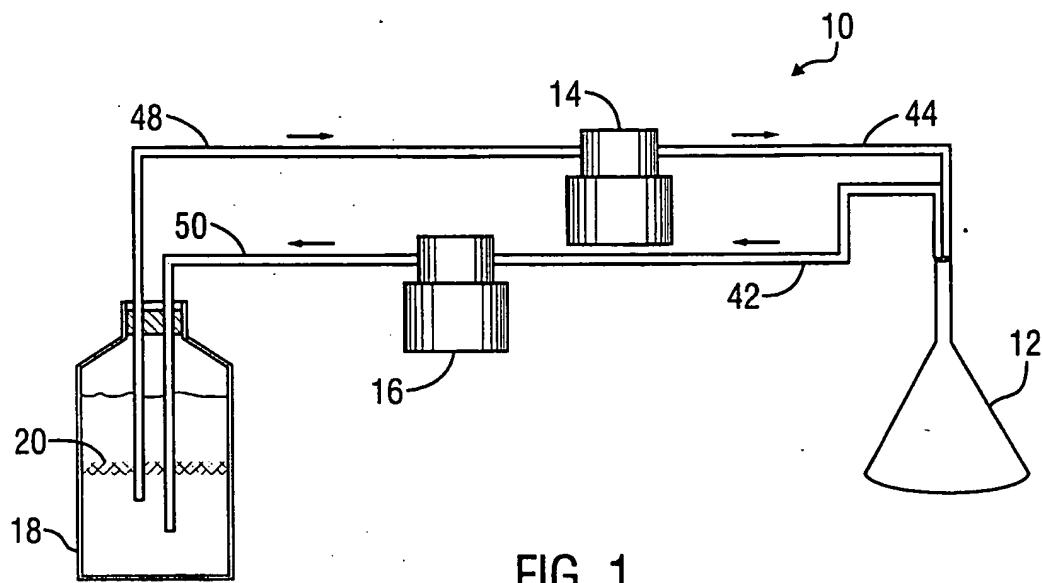


FIG. 1

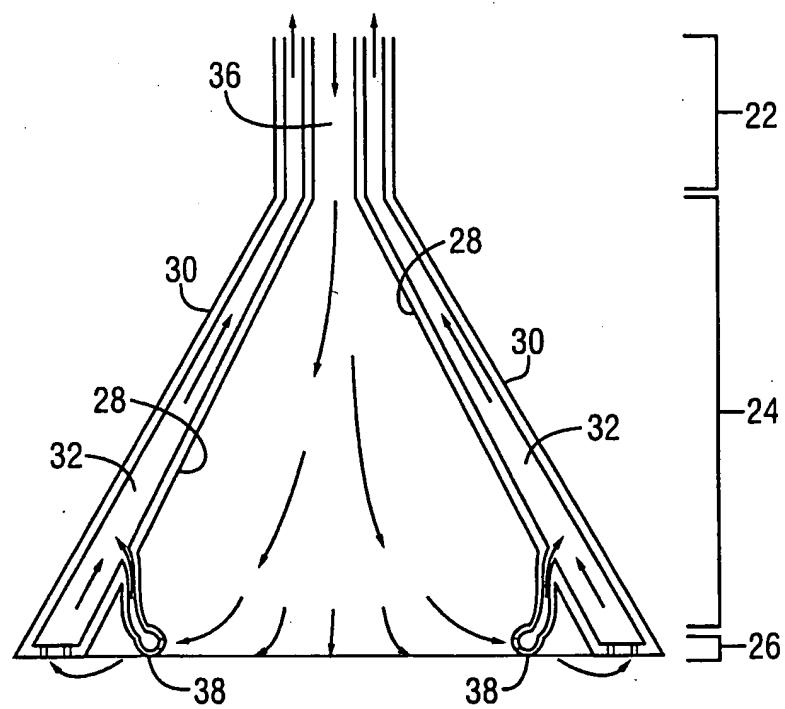


FIG. 2

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FIG. 3

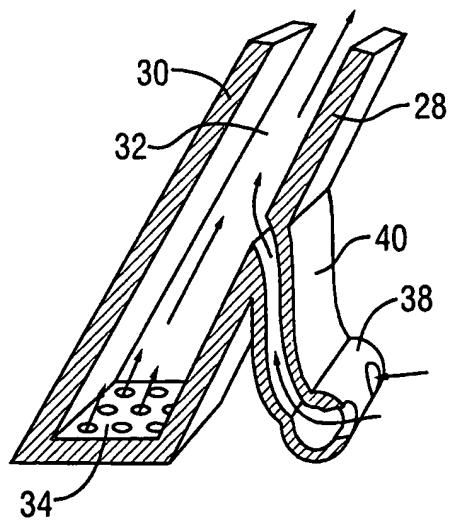
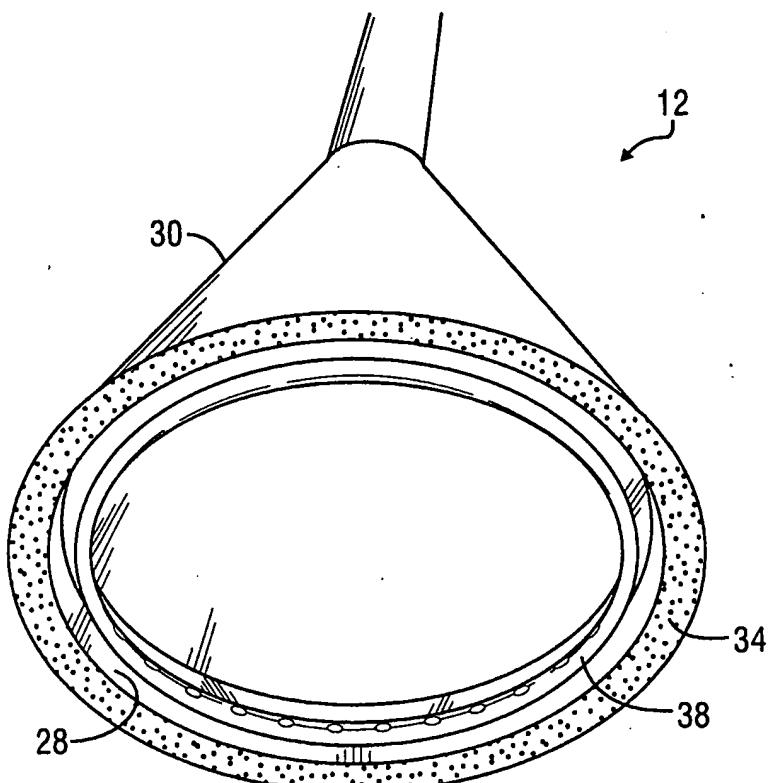


FIG. 4A

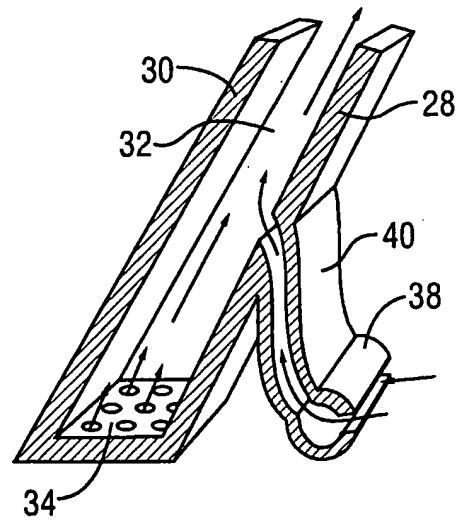


FIG. 4B

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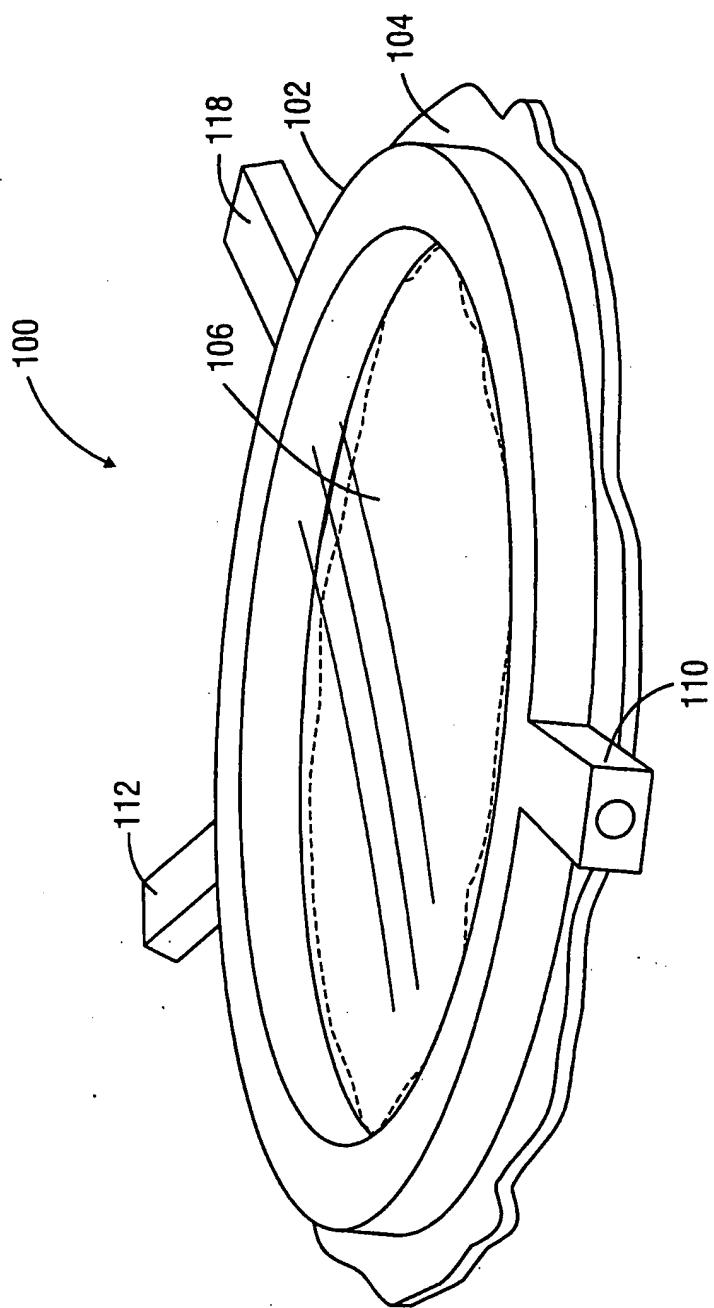


FIG. 5

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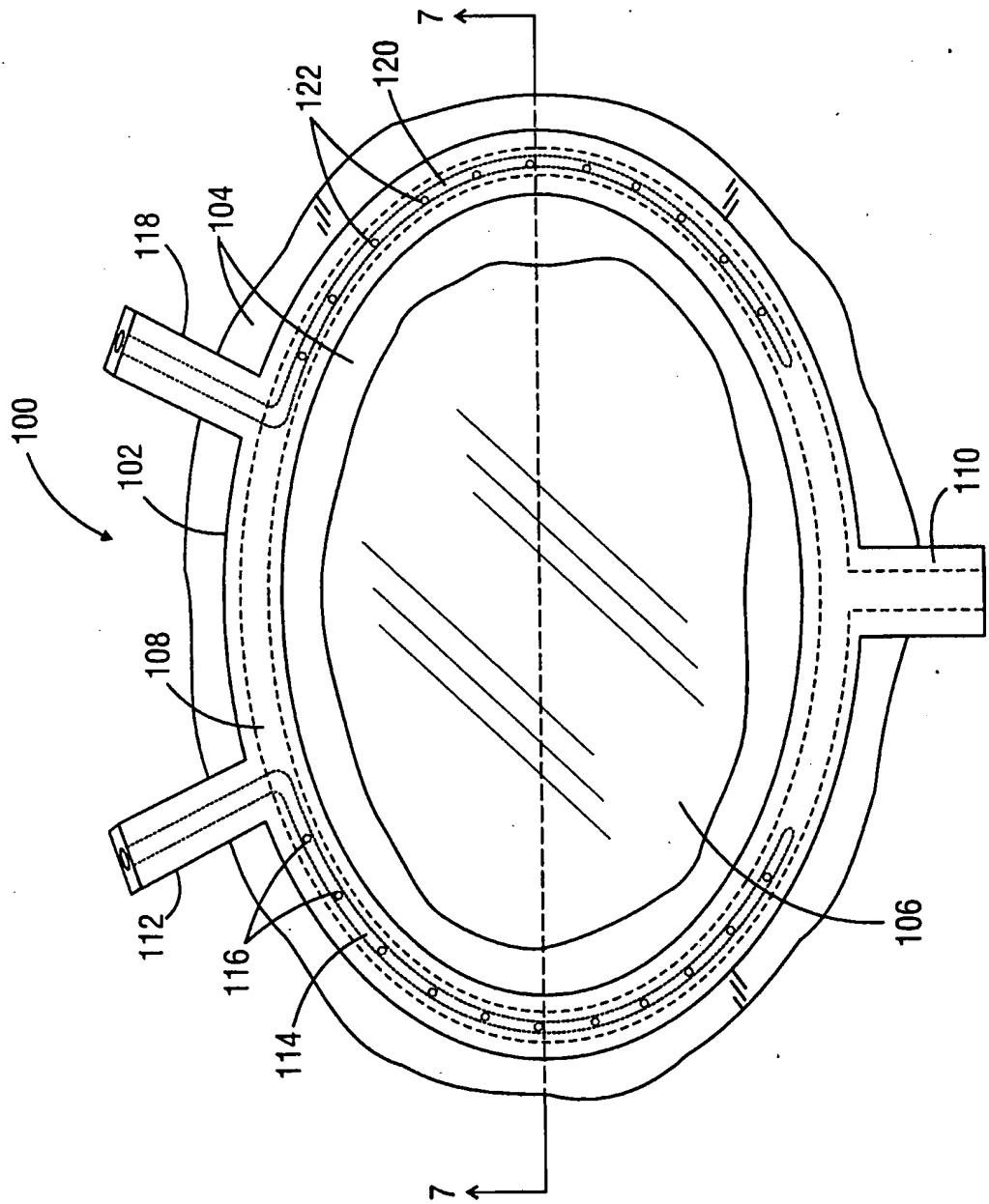


FIG. 6

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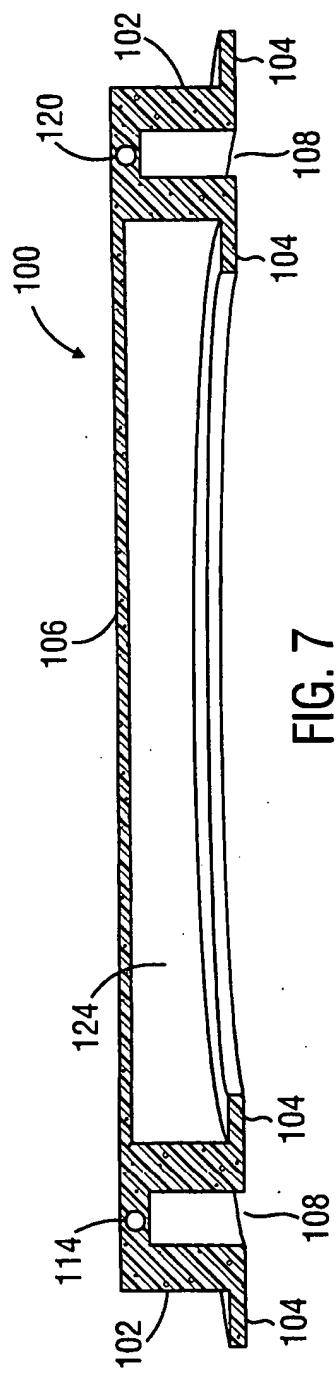


FIG. 7

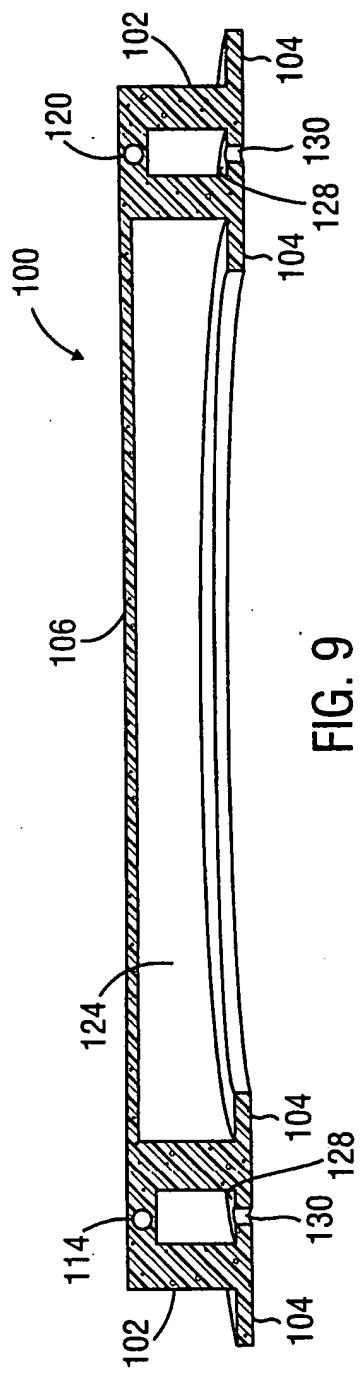


FIG. 9

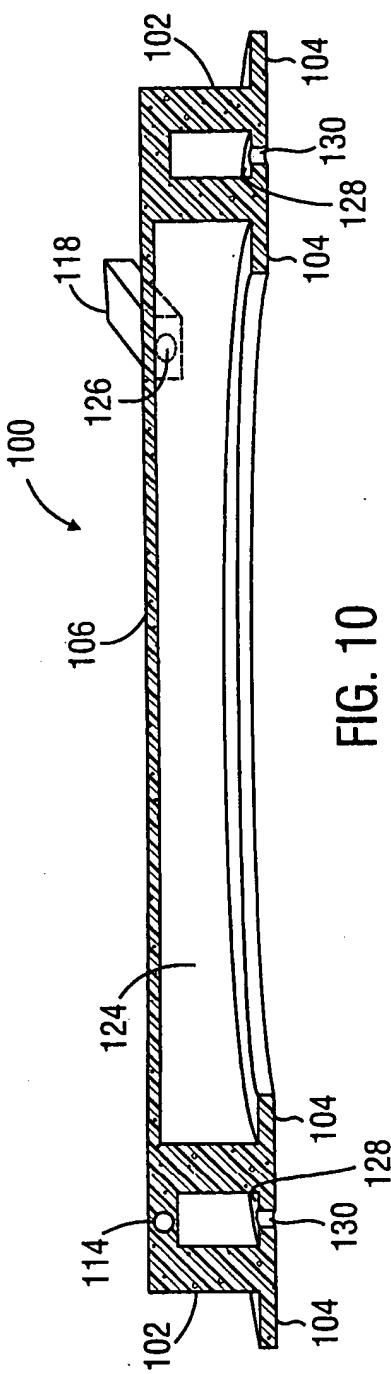


FIG. 10

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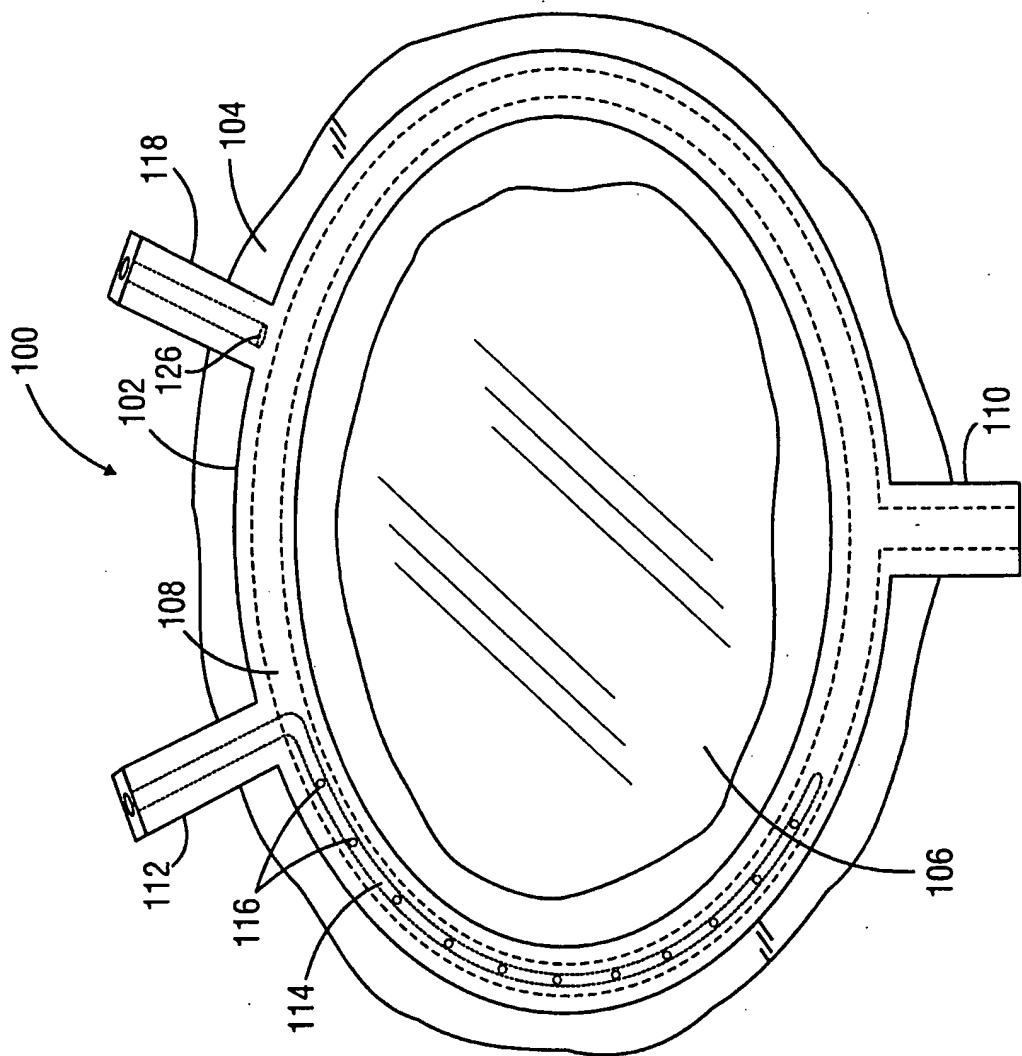


FIG. 8

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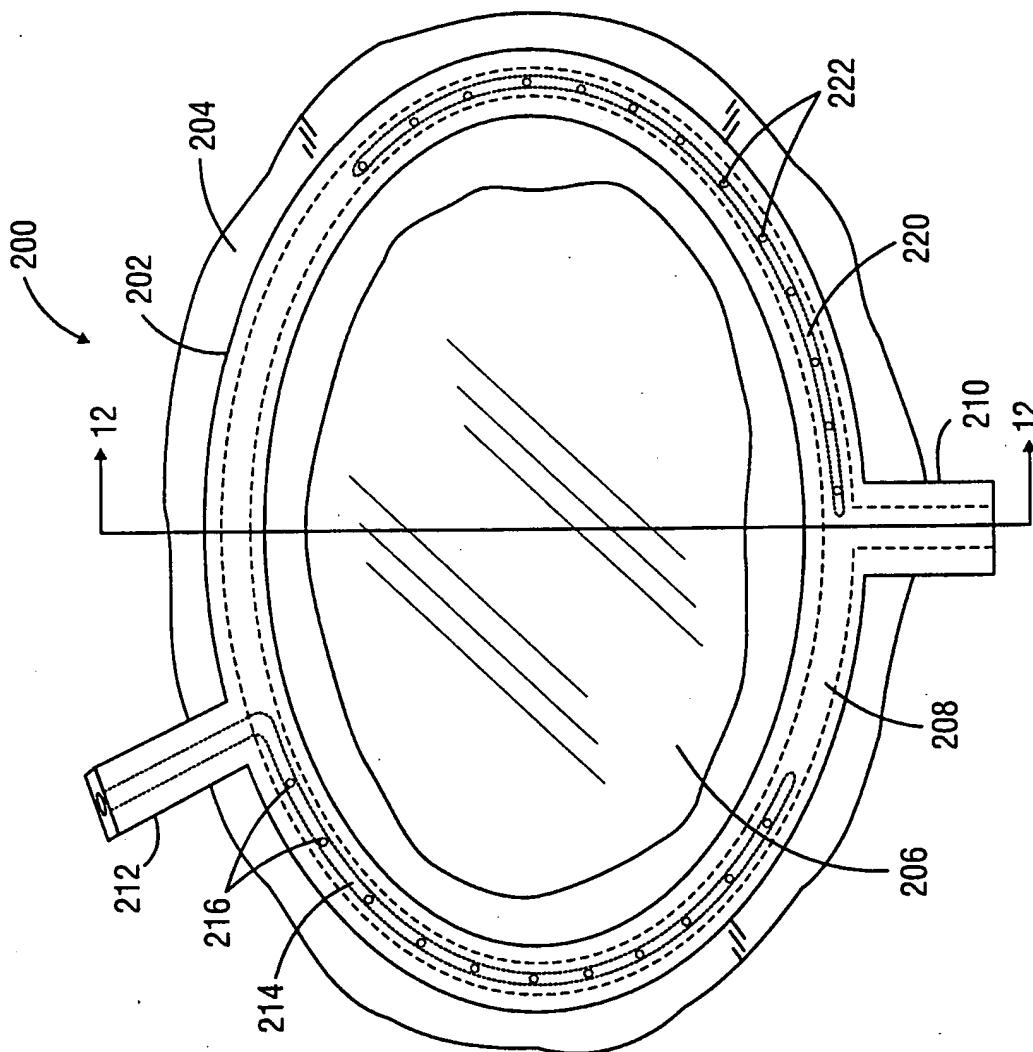
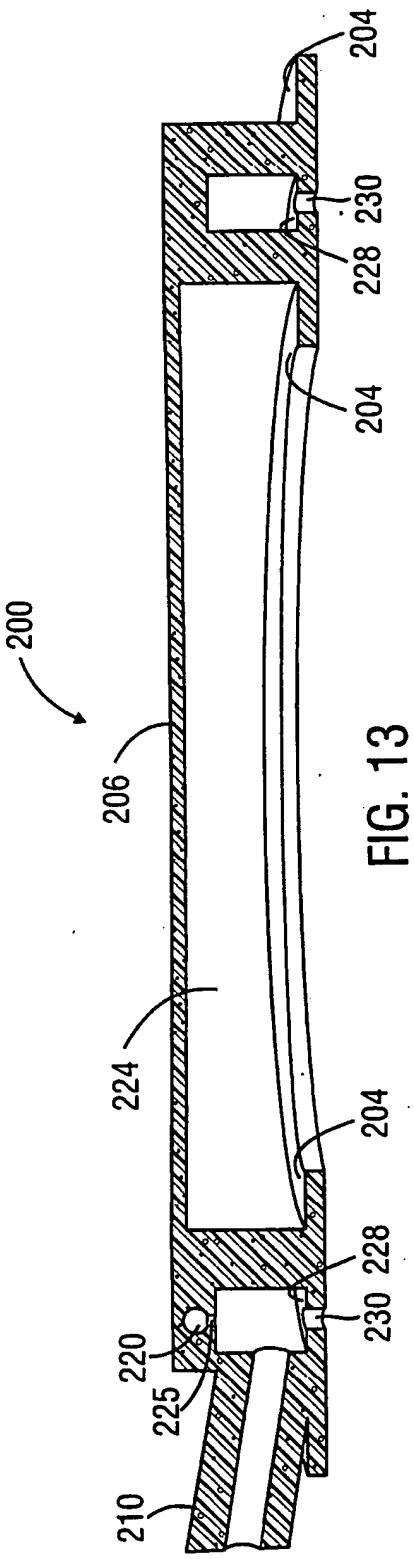
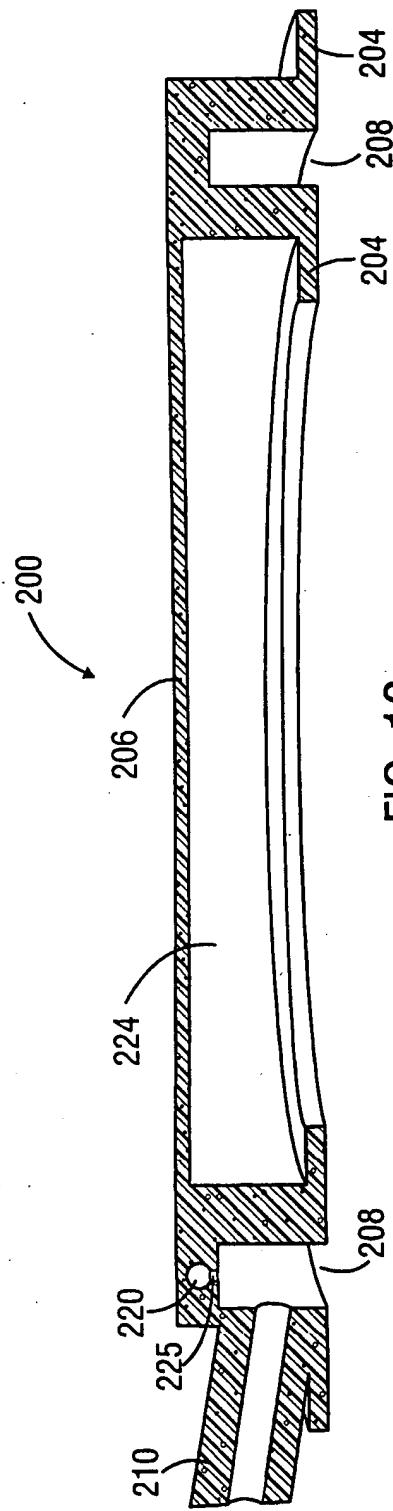


FIG. 11

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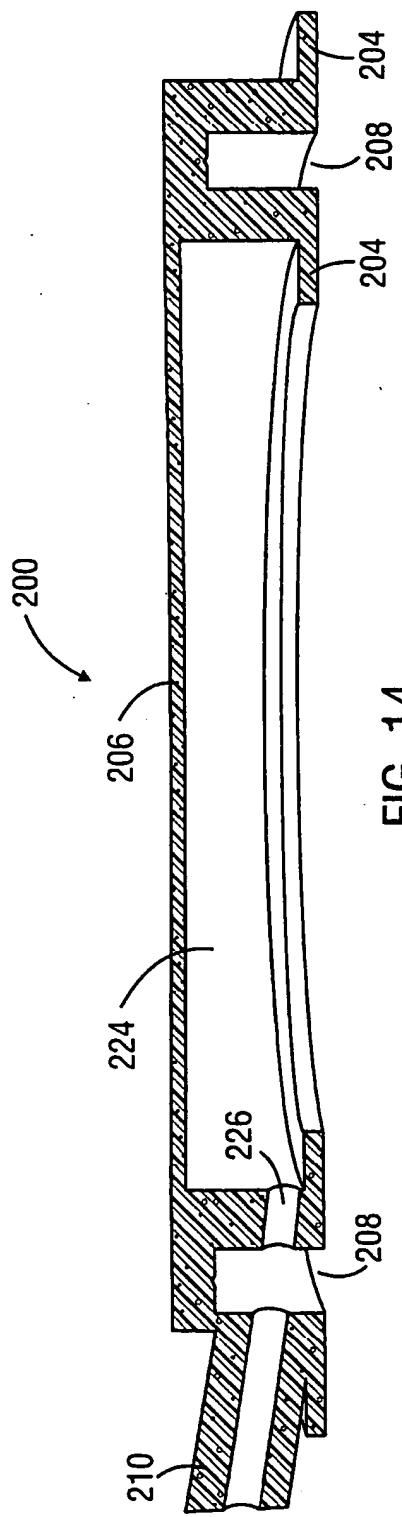


FIG. 14

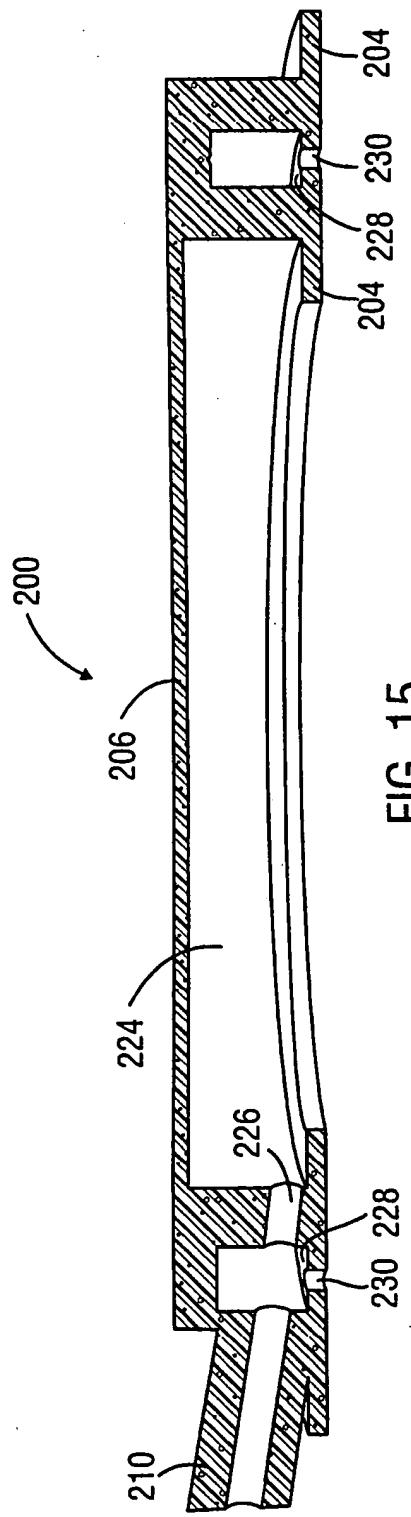


FIG. 15

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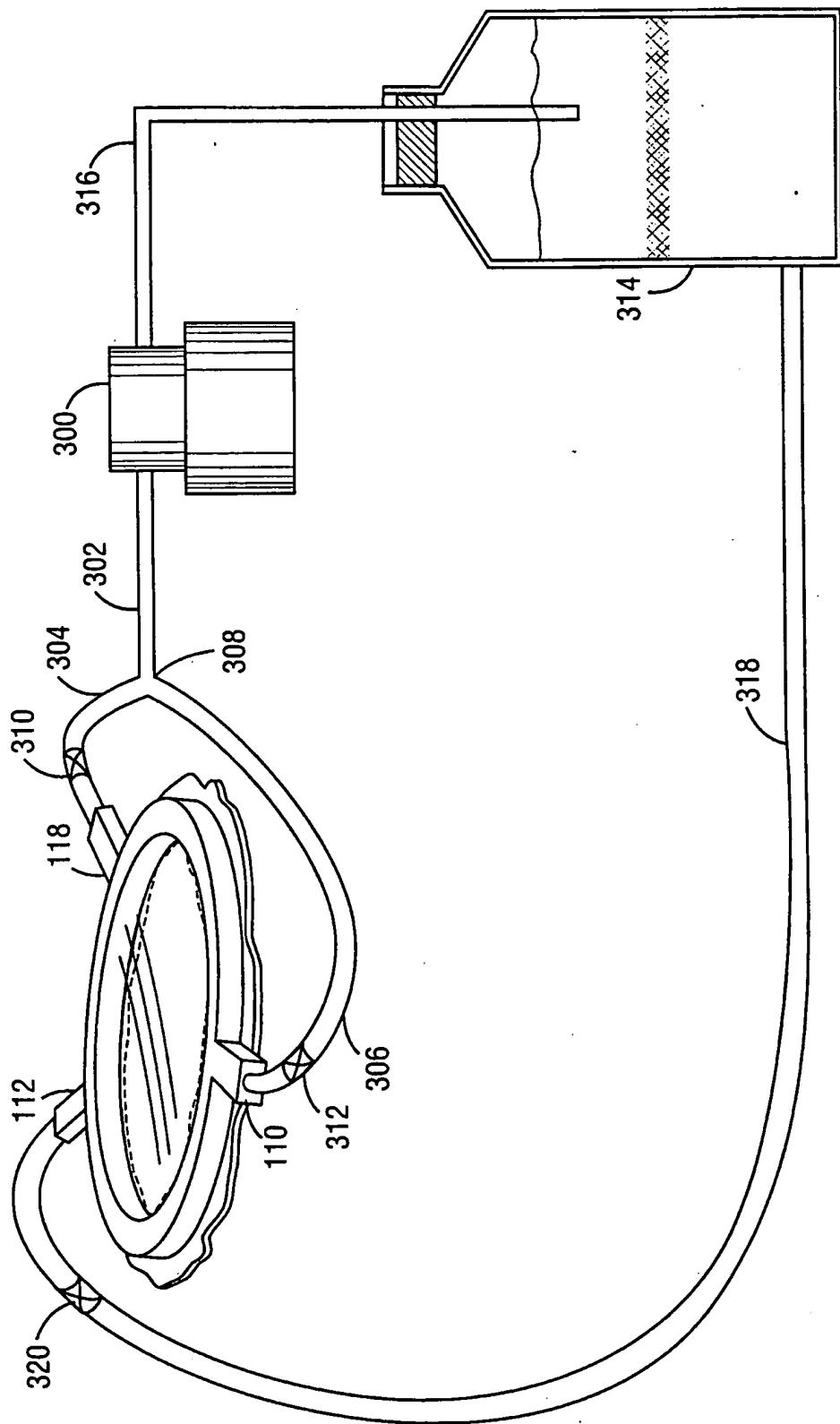


FIG. 16

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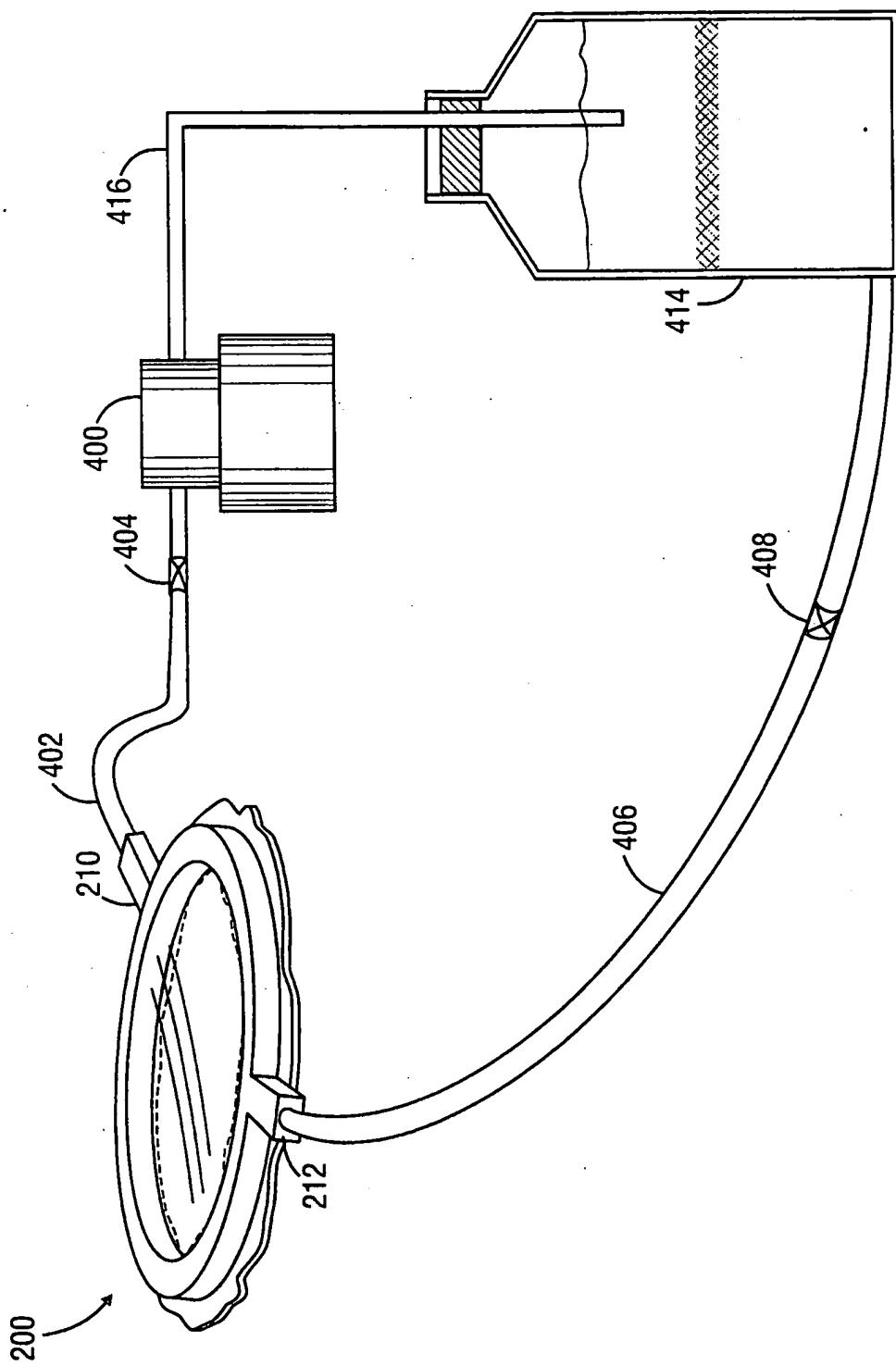


FIG. 17

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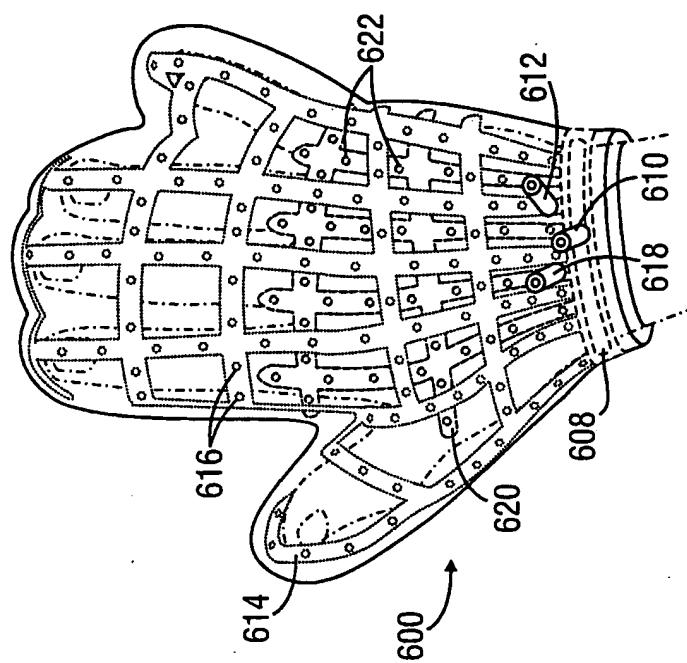


FIG. 19

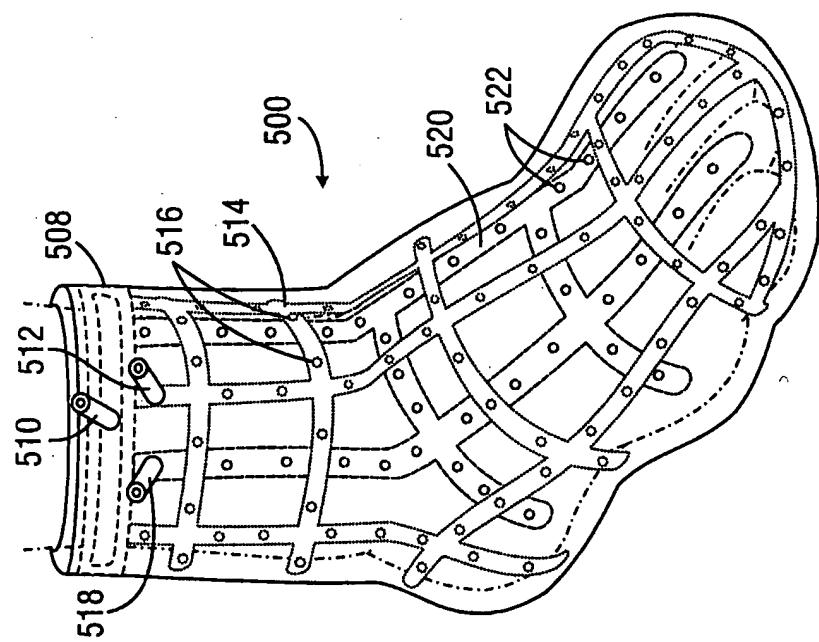


FIG. 18

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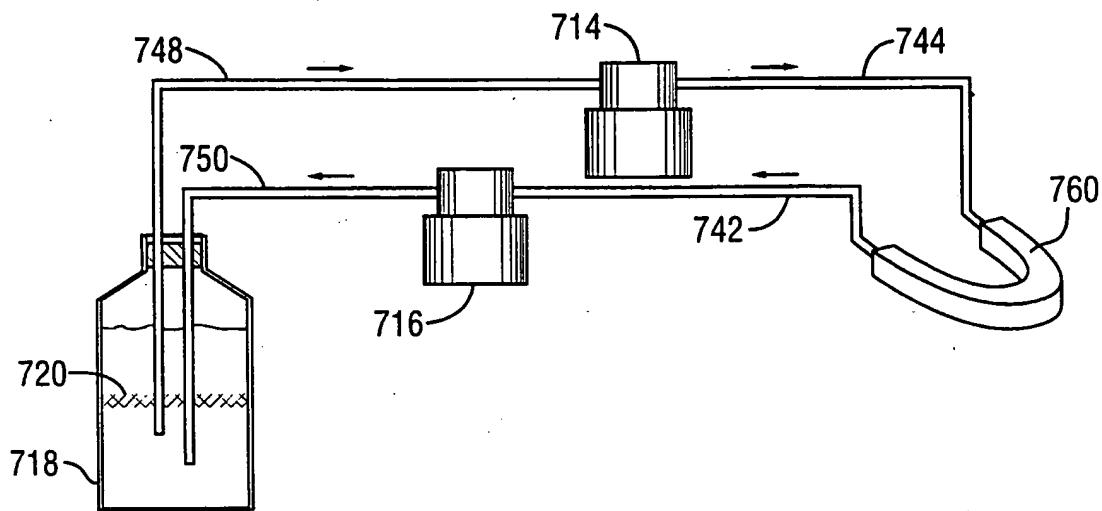


FIG. 20

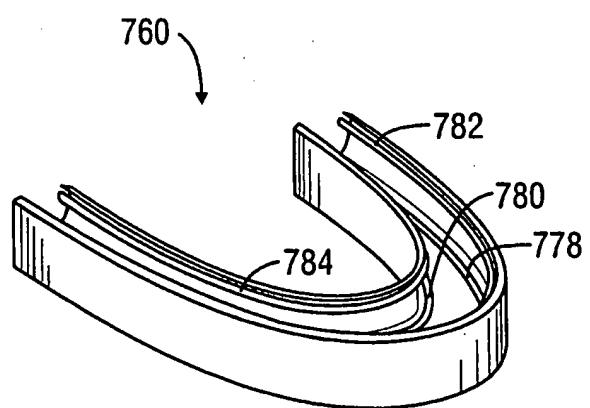
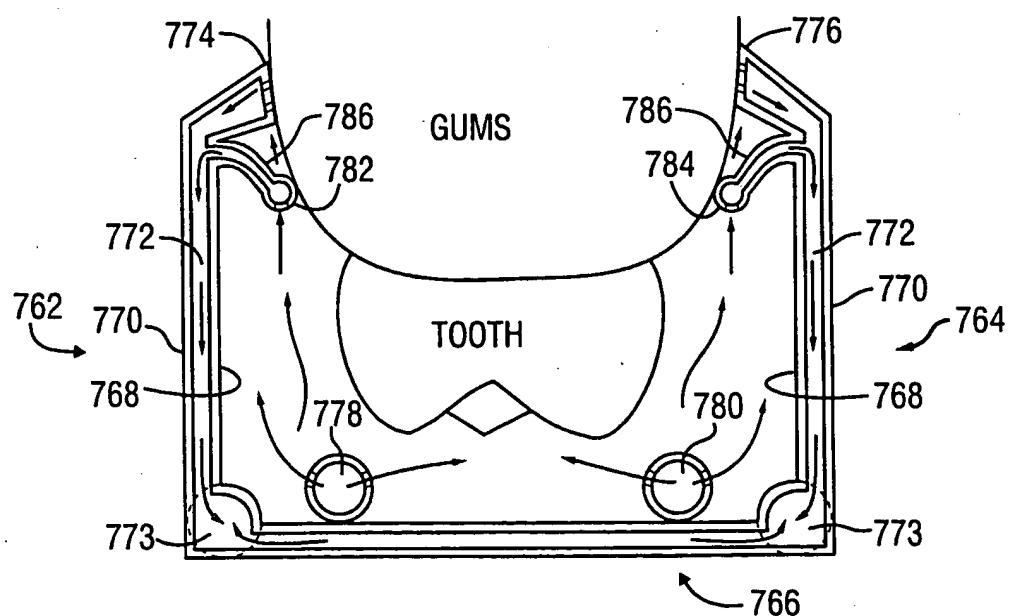
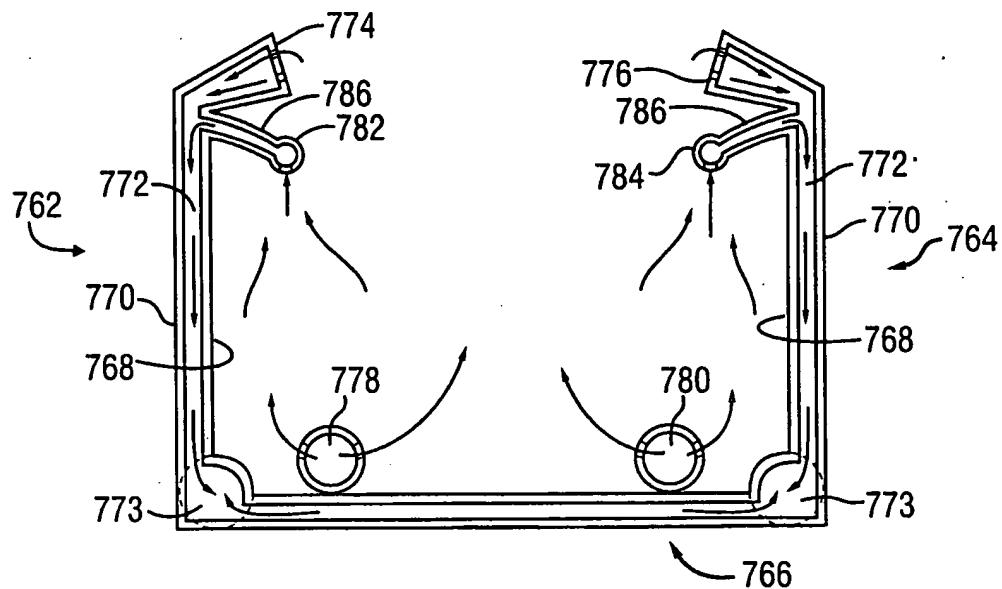


FIG. 21

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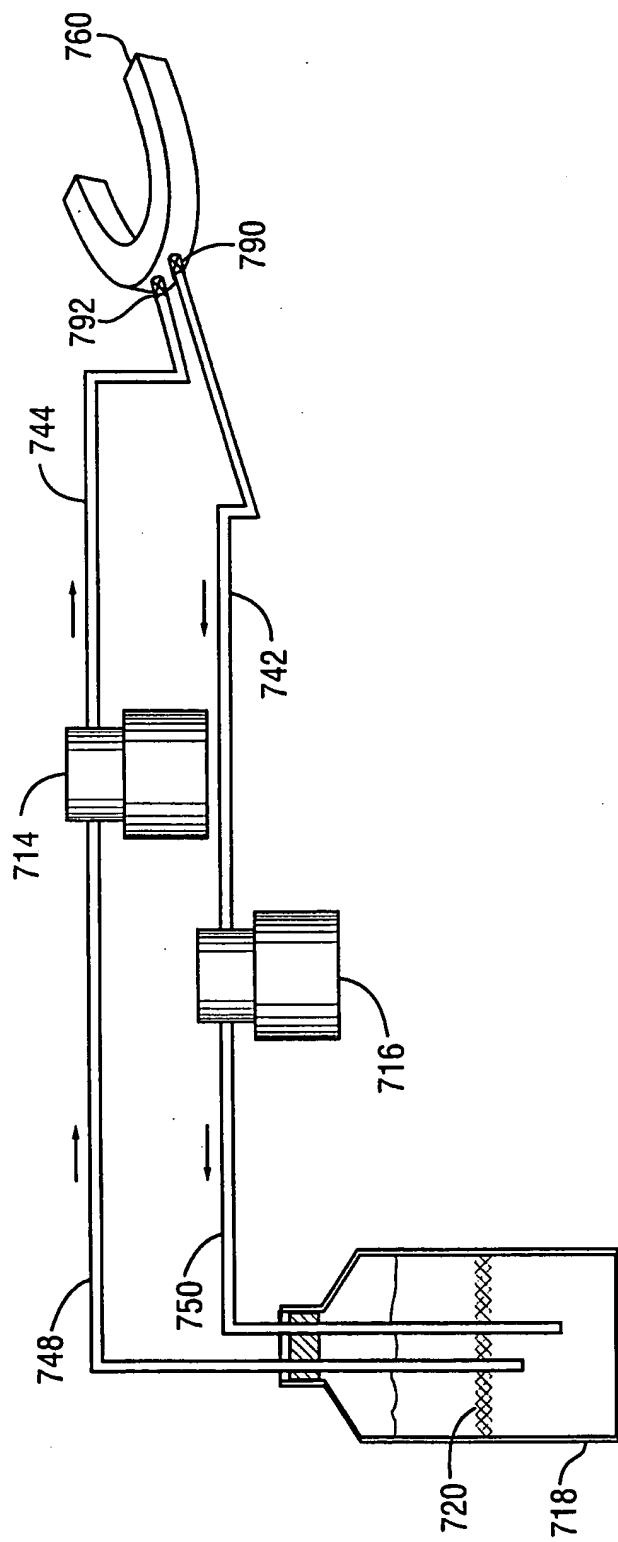


FIG. 24

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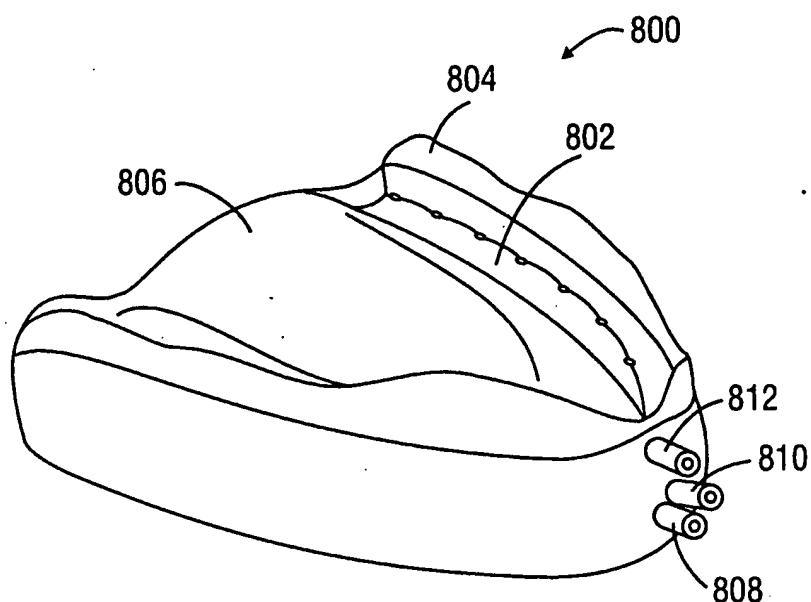


FIG. 25

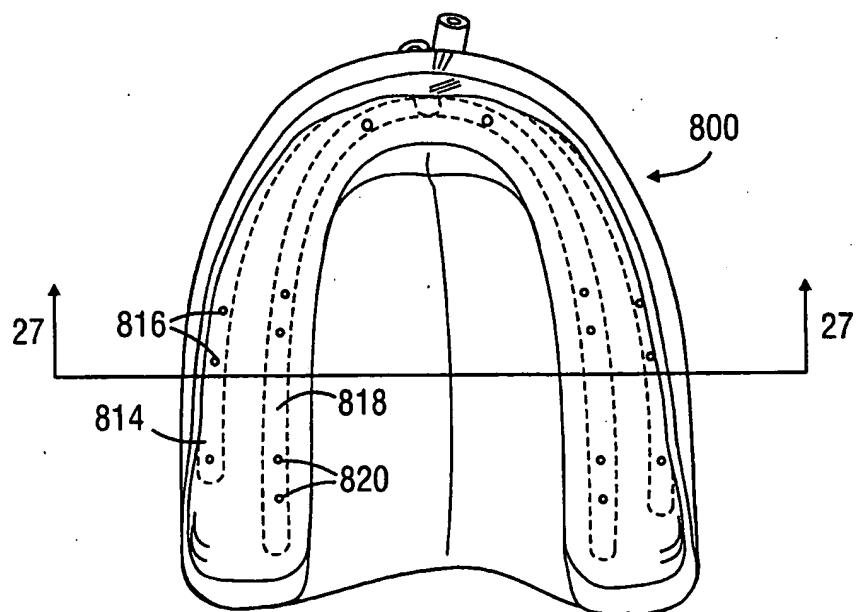


FIG. 26

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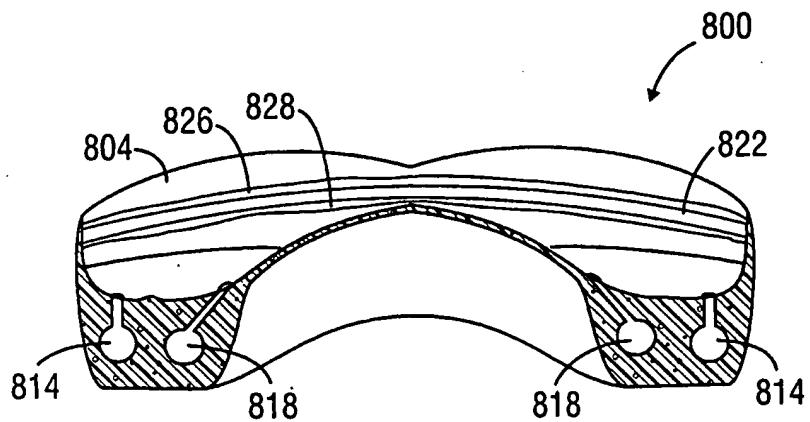


FIG. 27

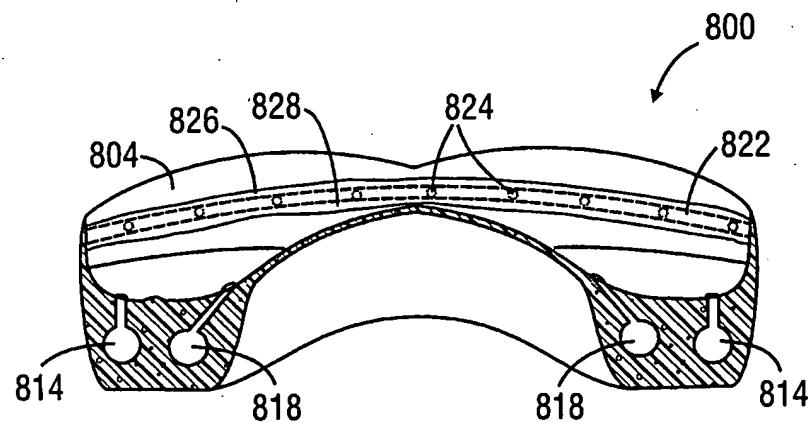


FIG. 28

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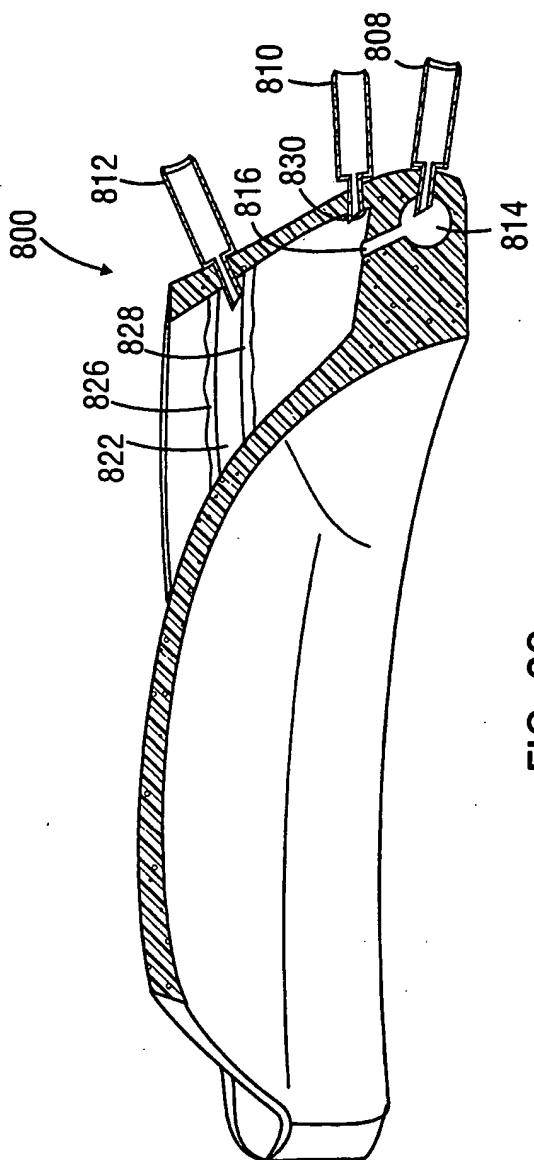


FIG. 29

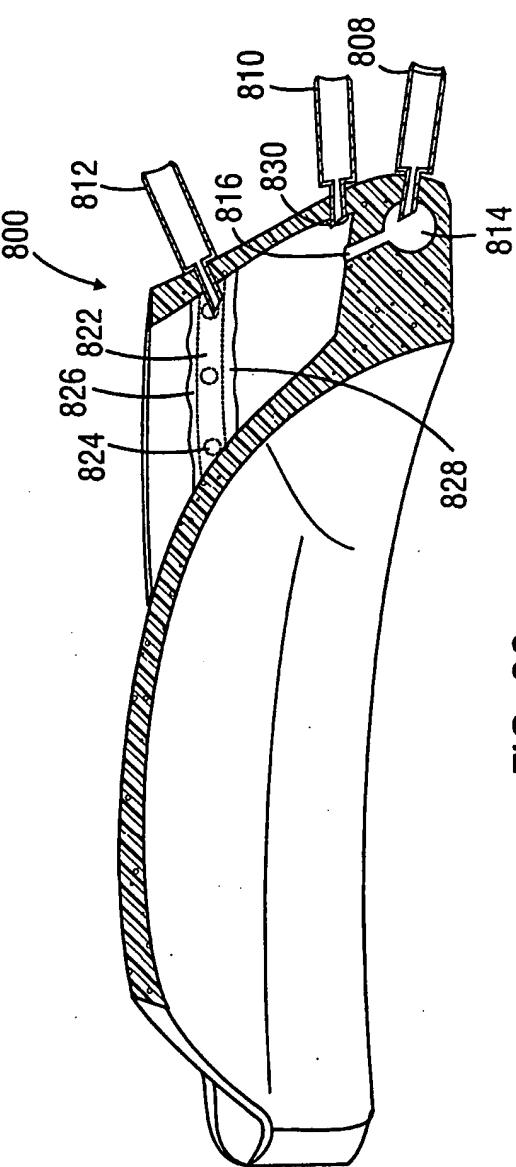


FIG. 30

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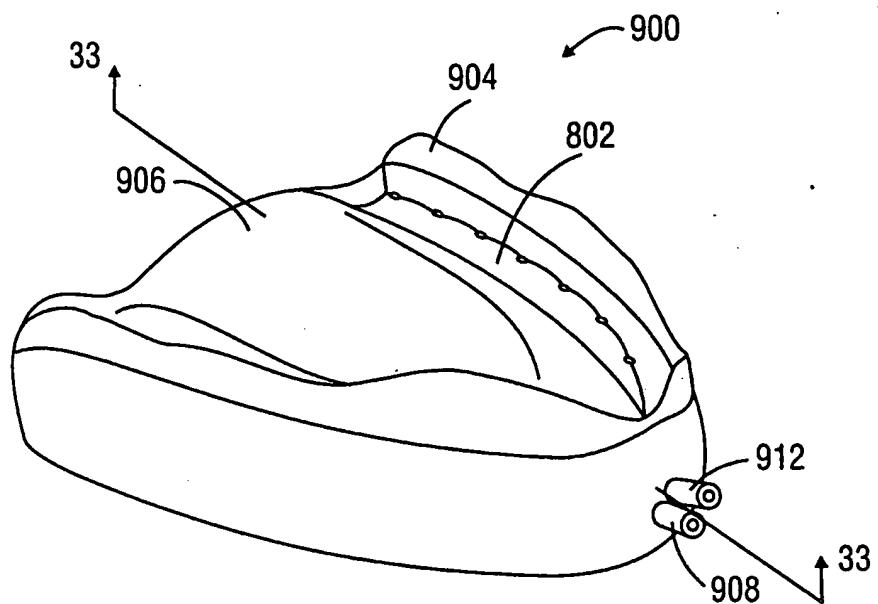


FIG. 31

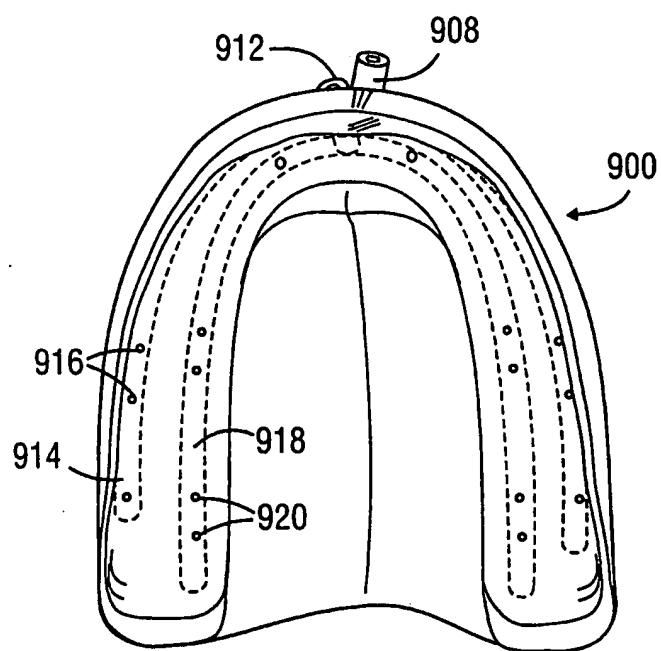


FIG. 32

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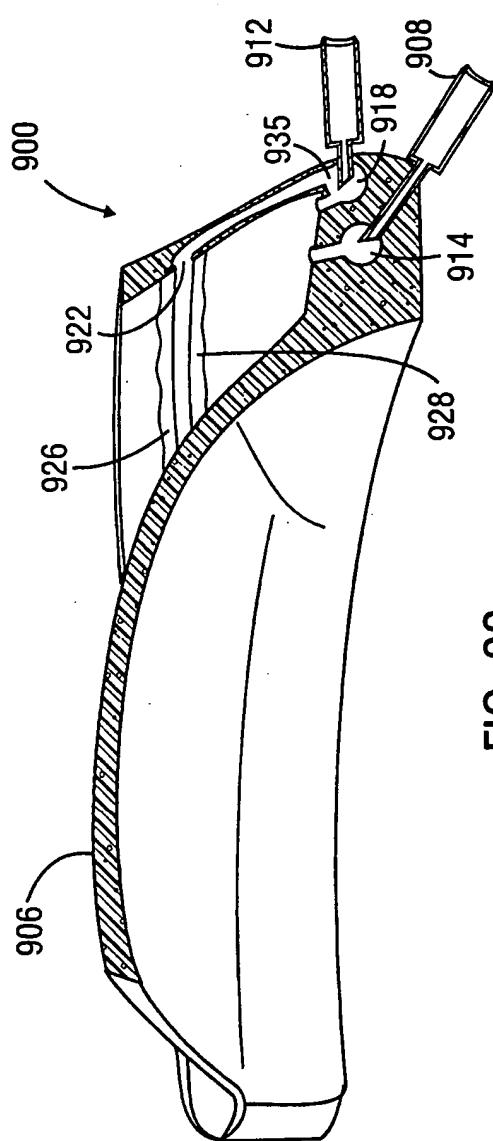


FIG. 33

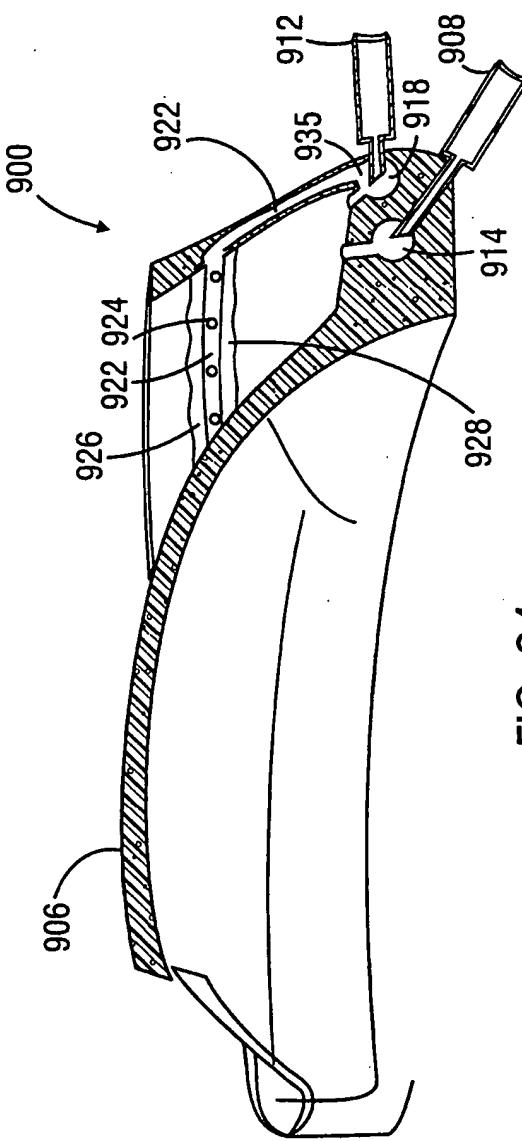


FIG. 34

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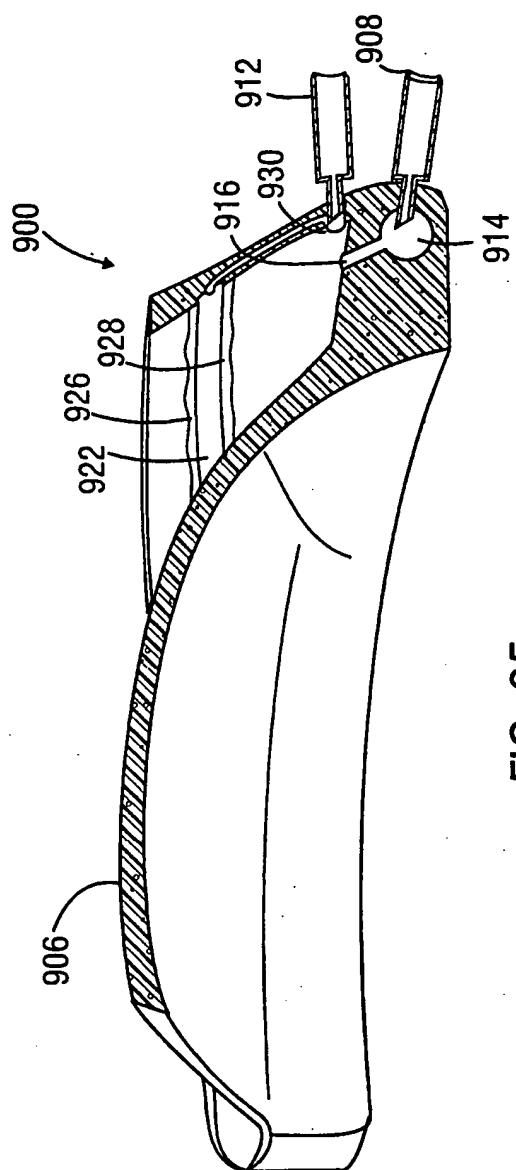


FIG. 35

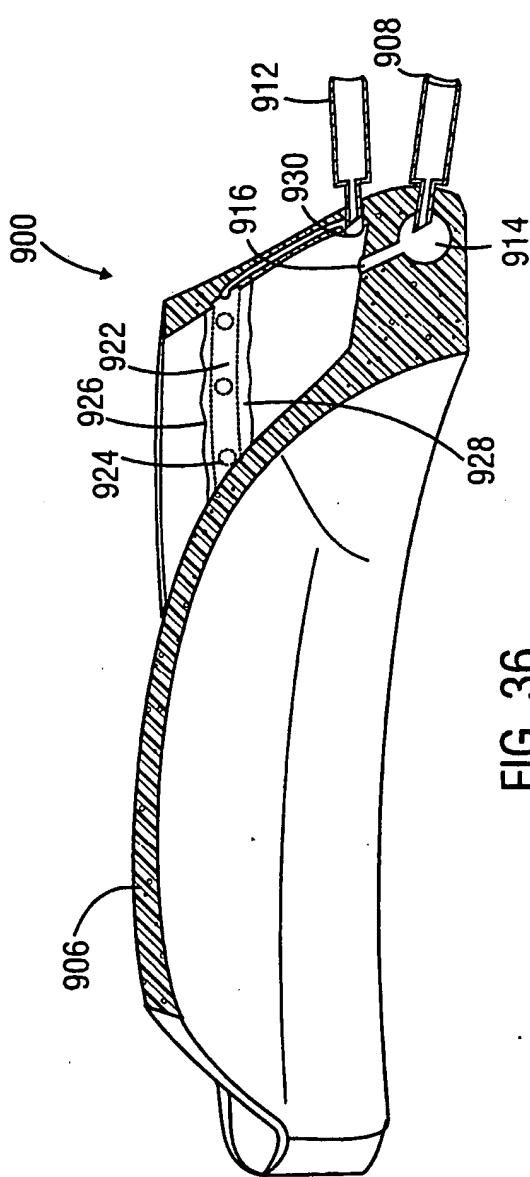


FIG. 36

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/03487

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61C 15/00; A61H 7/00  
US CL : 433/216; 601/164, 166

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 433/80, 215, 216; 601/160, 162, 164, 166

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 3,489,141 A (WARREN, JR.) 13 January 1970, entire document.	1-6, 9, 10, 17-25, 29-34, 36, 38-53 -----
Y		7, 8, 11-16, 26-28, 37
Y	US 3,574,239 A (SOLLERUD) 13 April 1971, entire document.	7, 8, 12-14, 26-28
Y	US 2,272,481 A (RINKES et al) 10 February 1942, page 2; and col. 1, lines 1-18.	11, 16, 28
Y	US 3,478,738 A (ALTMAN et al) 18 November 1969, col. 2, lines 37-49.	15

Further documents are listed in the continuation of Box C.  See patent family annex.

- \* Special categories of cited documents:
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- "E" earlier document published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search  
24 JUNE 1997

Date of mailing of the international search report

16 JUL 1997

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Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231  
Facsimile No. (703) 308-3230

Authorized officer  
JOHN J. WILSON  
Telephone No. (703) 308-2699

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## INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/03487
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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,732,580 A (FAVA) 15 May 1973, col. 4, lines 35-45.	37
A	US 2,113,253 A (GRAY) 05 April 1938, page 1; and col. 2, lines 23-45.	13
A	US 4,353,359 A (MILBAUER) 12 October 1982, col. 6, lines 35-42.	15, 16
A	US 5,145,367 A (KASTEN) 08 September 1992, col. 3, lines 17-21.	7